NCI CTRP Registration Site Help Topics

Version 4.3.1

Topic Links

This page is simply a wiki shortcut.
This page displays subject matter that is included, in context, in many of the web pages that constitute the CTRP application user's guides.

You can send this page to a printer or convert it to a PDF, HTML, or Word document. See Printing and Exporting Wiki Pages.

Getting Help

This page contains select topics that help you to understand and use the NCI CTRP Registration application. You can find more comprehensive documentation in the NCI CTRP Registration User's Guide.

- Email: ncicbiit@mail.nih.gov
- Call: 240-276-5541

When submitting support requests, please include:

- Your contact information, including your telephone number
- The name of the application/tool you are using
- The URL if it is a Web-based application
- A description of the problem and steps to recreate it

- The text of any error messages you have received

Contacting the Clinical Trials Reporting Office

If you have questions or comments regarding this document, or other CTRP topics, contact the Clinical Trials Reporting Office (CTRO) at ncictro@mail.nih.gov.

Adding Sites

You can add your organization as a participating site to any *Abbreviated trial that meets the following criteria:*

(To add your organization as a participating site to a Complete trial, contact the lead organization.)

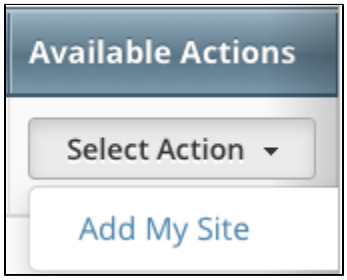
Trial Attribute	Requirement
Lead Organization	Not an organization in RSS
Your Organization	Not currently participating in the trial
Trial Processing Status	Accepted or beyond

Once added, you can update your site's record at any time.

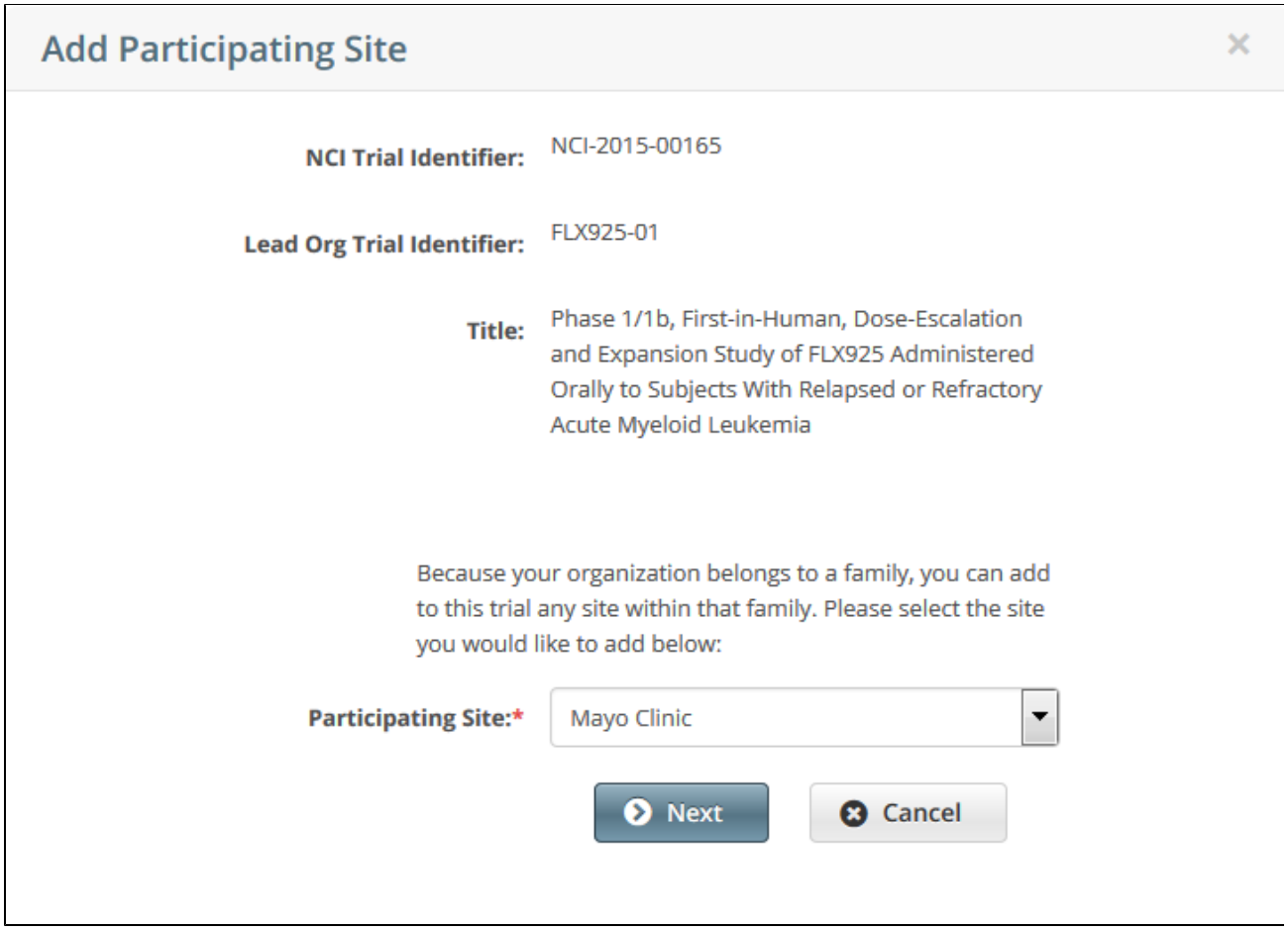
Trial information that you can update after adding your site includes the following:

- Organization's local trial identifier
- Site principal investigator
- Organization family's program codes
- Site recruitment status and dates

How to Add Your Organization as a Participating Site

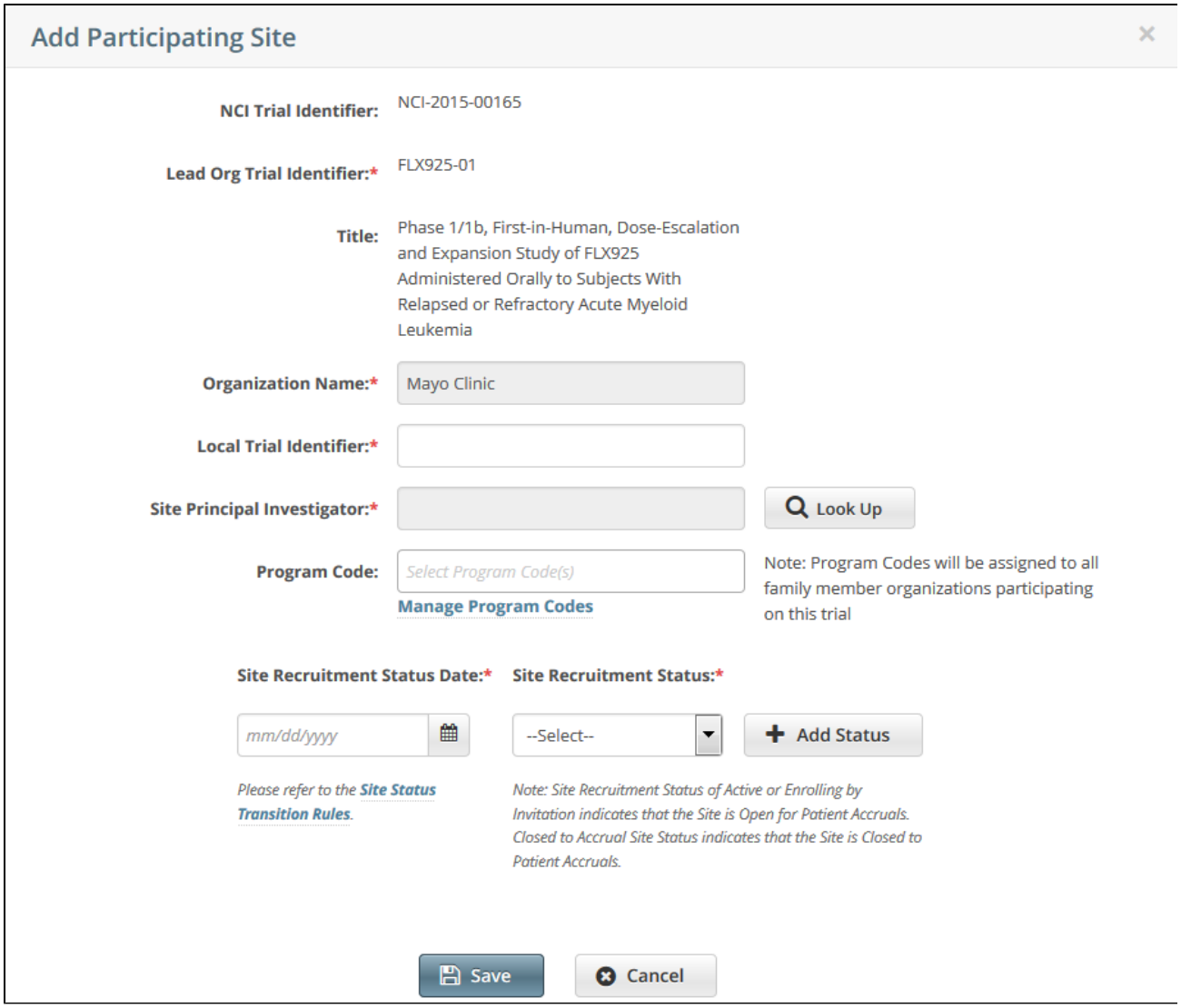
1. Select the trial that your site is participating in. The **Available Actions** column in the search results table displays actions currently available for the trial.


2. In the **Available Actions** column, click the **Select Action** button and click **Add My Site**. The Add Participating Site page appears.



The Participating Site list contains all organizations in the Organization Family associated with your CTRP account.

3. From the **Participating Site** list, select the organization that you want to add to this trial. Click **Next**. Another Add Participating Site page appears.



4. Select or enter the appropriate information in the text fields and drop-down lists. The following table describes the fields. An asterisk (*) indicates a required field.

Field	Description/Instructions
Local Trial Identifier *	Enter the identifier used at the participating site.
Site Principal Investigator*	Click Look Up to search for, and select, the site principal investigator.
Program Code	Optionally, select one or more program codes for the trial. The Program code field lists all program codes available for the organization family.

5. Add site recruitment status information:
    a. Select or enter the appropriate information in the text fields and drop-down lists. The following table describes the fields. An asterisk (*) indicates a required field.

Field	Description/Instructions
Site Recruitment Status Date *	Enter the date on which the current trial status became effective. To ensure that you record valid status dates, review the information provided in Trial Status Date Rules in the CTRP.

Site Recruitment Status*	Select the current stage or state of the trial or study. The system validates all status transitions when you save a status record. If you add or update a status transition that does not conform to the rules provided in Trial Status Transition Rules in the CTRP, the system displays errors and/or warnings. *Warnings* indicate that fixing the status record is optional; you do not have to resolve the transitions. However, *Errors* indicate that you must resolve the transitions by correcting trial status records.

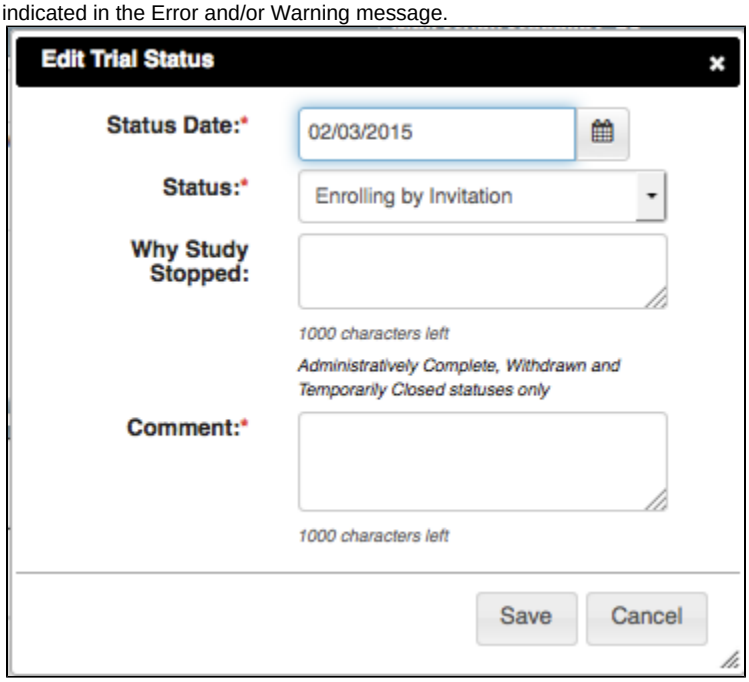
b. Click Add Status. The Site Recruitment Status History section appears, displaying the site recruitment information you entered.

Site Recruitment Status- No Warnings or Errors

Site Recruitment Status- With Warnings and an Error

c. Repeat the process of entering a status date, entering a status, and clicking **Add Status** until you have entered all statuses for the site.

6. If the system displays Errors or Warnings indicating that the status you added is invalid, do one of the following.
   a. To edit the status, in the **Actions** column, click the **Edit** icon. Then, in the **Edit Trial Status** dialog box, make changes as indicated in the Error and/or Warning message.



   b. To delete the status, in the **Actions** column, click the **Delete** icon. Enter a comment indicating the reason why you deleted the record, and then add the correct status information.

8. Click **Save**. Your information is added to the trial details.

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Amending Trials

In your role as trial owner (original submitter or current owner), you can amend only *Complete* trials. The trials you own are listed when you use the Search My Trials feature. Refer to Searching for Trials. In addition to rules provided in Registering New Trials, the following rules apply to amendments:

- You can create a new NIH grant record only if you can provide all of the following details:
  - Funding Mechanism
  - NIH Institution Code
  - Serial Number
  - NCI Division/Program
- You can not change the following existing information:
  - NCI trial identifier number
  - NIH grant number
  - IND/IDE serial number
- The following list is the minimum set of required documents that must be submitted with each amendment:
  - Protocol document.
  - IRB approval document.
  - A change memo document or protocol highlighted document:
    - A change memo is a document that contains a summary of changes as compared to the original, or last amended, trial submission.
    - A protocol highlighted document is a document that has been marked up, with or without using a Track Changes feature.
  - List of participating sites and contact information (for multi-site trials, if not included in the protocol document).
  - Informed consent (if not included in the protocol document) and only when there are documented changes to the consent.

When you are submitting an amendment, we recommended that you provide any additional documents that you think will be useful to the CTRO for reviewing and processing the amendment document.

> A trial may have more than one owner. Review the recorded information carefully to see if another owner has modified the trial.

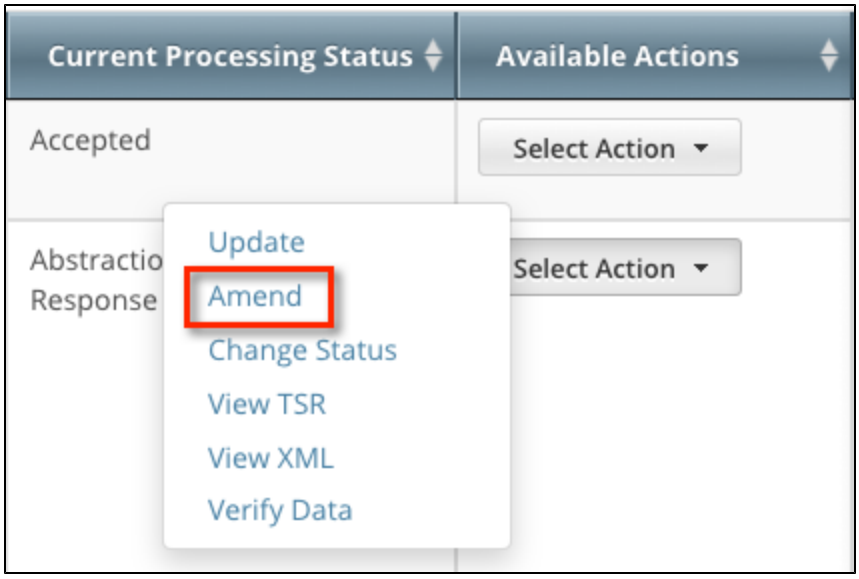
Examples of Amendments

The following are examples of amendments that the Amend Trial feature accommodates.

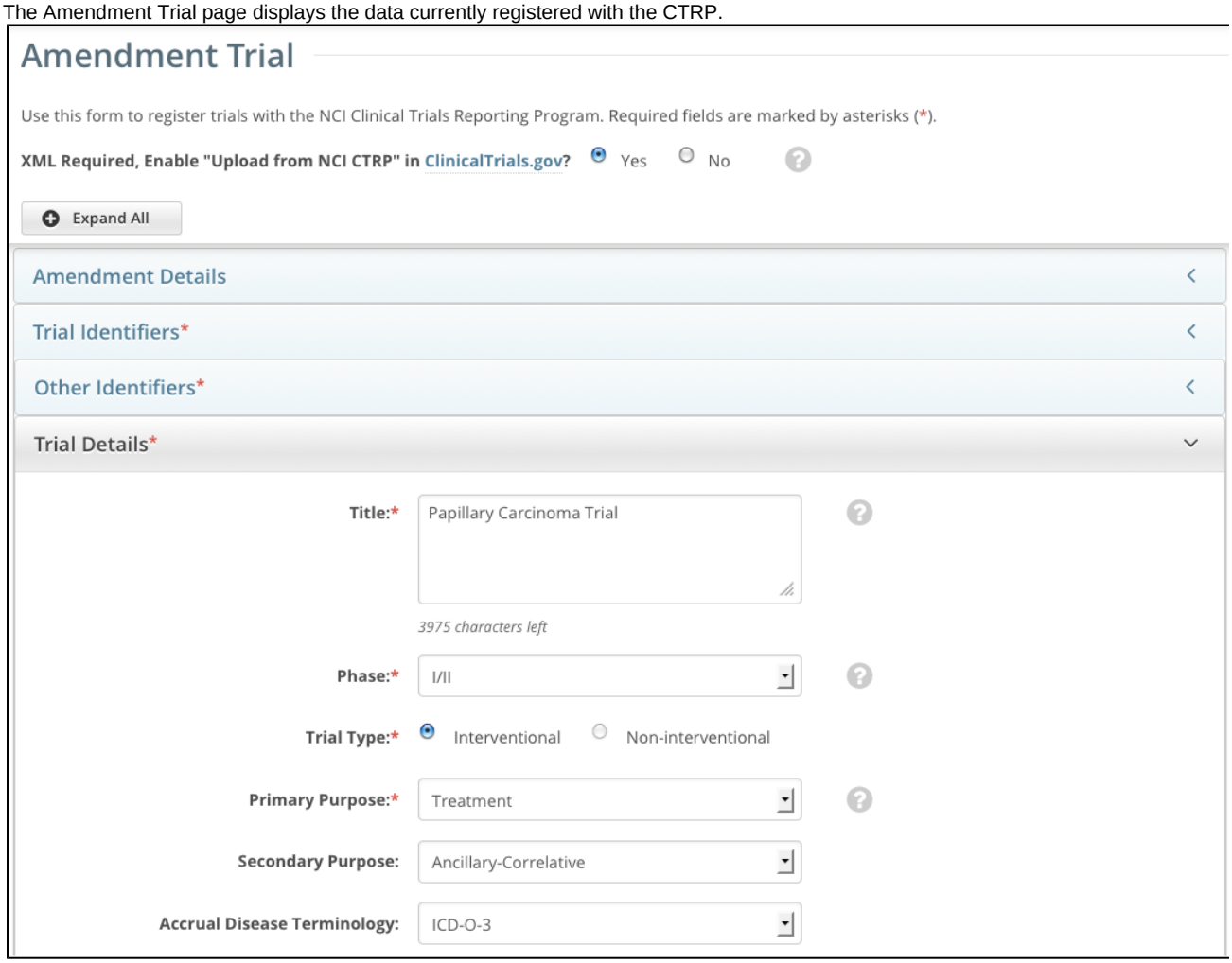
- **Dose Escalation Amendment** (change in the number of patients treated at a given dose level)
- **Change in Sites Open to Patient Accrual**
- **Change in Principal Investigators**
- **Change in Risk to Participants** (new risk identified [new CAEPR], changes made as a result of an updated Severe Adverse Event)
- **Scientific Change** (opening an arm, adding a new arm, closing an arm, changing objectives, changing statistical analysis, adding correlative studies, increase or decrease in the accrual goal, changing from Phase I to Phase II, additional data points)
- **Correction of Typographical Errors which Change Scientific Meaning** (mg vs. mcg)
- **Eligibility Change** (change to the inclusion or exclusion criteria)
- **Therapy Change** (change in dose, adding another agent, change in administration, change in route)

How to Amend Trials

1. On the toolbar, click **Search > Clinical Trials**.
   The Search Trials page appears.
2. Click **Search > My Trials**.
   The Search Results page displays the results of your search and actions available (if any) for each record.



3. In the **Available Actions** column, click **Select action > Amend**.
The Amendment Trial page displays the data currently registered with the CTRP.



4. In the Amendment Details section, select or enter the appropriate information in the drop-down lists and text fields. The following table describes the fields. An asterisk (*) indicates a required field.

Field Label	Description/Instructions
Amendment Number	Enter an appropriate number.
Amendment Date*	Select or enter an appropriate date.

5. Select or enter the appropriate information in the remaining text fields and drop-down lists, following the instructions provided in Registering New Trials .

If a trial (*Complete* or *Abbreviated*) reaches any of the following statuses, the system closes the trial at all participating sites, and sets their trial statuses to match the status of the trial that closed:

- Closed to Accrual
- Closed to Accrual and Intervention
- Administratively Complete
- Complete

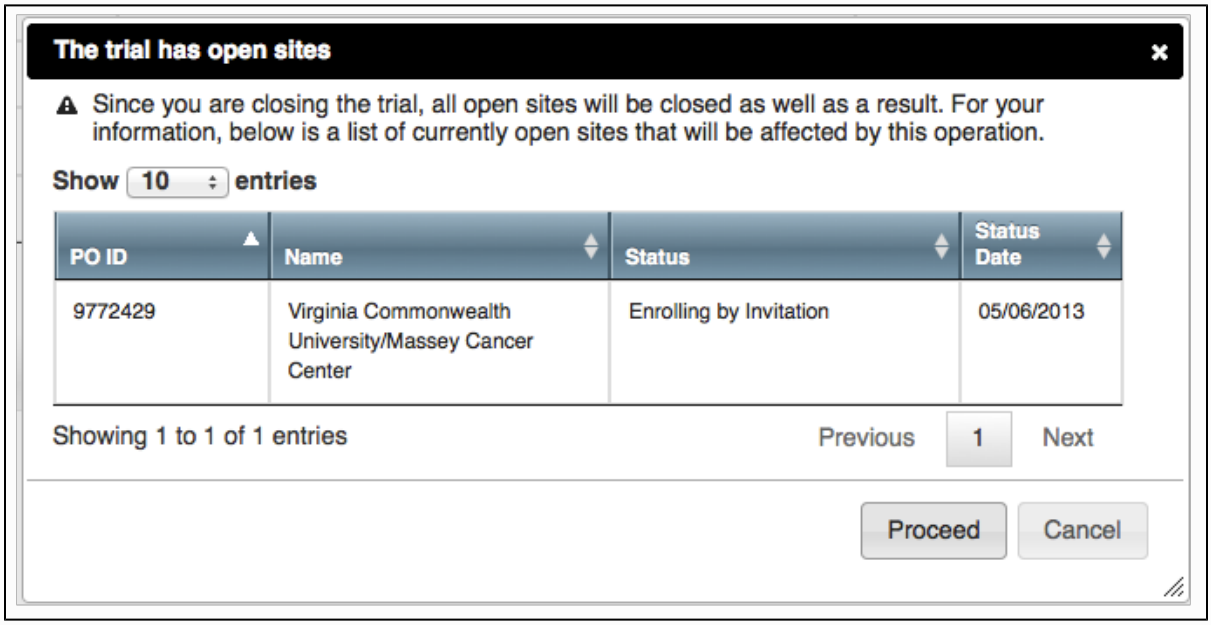
The system adds a closure status to each site only if all of the following conditions are met:

- The trial has a closure status as the most recent status.
- The site status history does not have any closure status, regardless of site status date.
- The trial closure status date falls after the latest site status date.

When inserting a new participating site status record, the system performs the following actions:

- Uses the trial's closure status as the site closure status.
- Uses the trial's closure status date as the site closure status date.
- Adds the following comment in the comments field: The CTRP application automatically closed this site because the trial was closed.

The system displays the following warning if you enter any of the statuses above:



You are required to provide information for all fields marked with an asterisk (*).

You can select a different disease code only if the trial has not accrued any subjects to date.

6. Review the amendment. See Reviewing and Submitting Trial Amendments .
7. Submit the amended trial to the CTRP.
   The system sends you an email notification — with the details of what has changed — whenever you amend accepted trials.

A trial can accumulate program codes from different organization families. For example, a participating site might belong to a different organization family than the lead organization. When you amend a trial, the Program Code field displays all codes from the master list for the organization family of the lead organization.

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Converting Documents to PDF

Microsoft provides instructions for converting files to PDFs both on their website and in the Help documentation in each of its applications.

> When searching for help, use the search term "save file as pdf".

You don't need a document converter in Mac OSX. Instead, *print* your documents to a PDF file.

How to Convert Text-Based Files to PDFs in Mac OSX

1. Open your text file in its original format (.doc, .xls, etc.)
2. Click **File > Print**.
3. In the **Print** window, click the **PDF** button at the bottom-left and select the **Save as PDF** option.
4. Choose the location, rename your PDF file, and then click **Save**.

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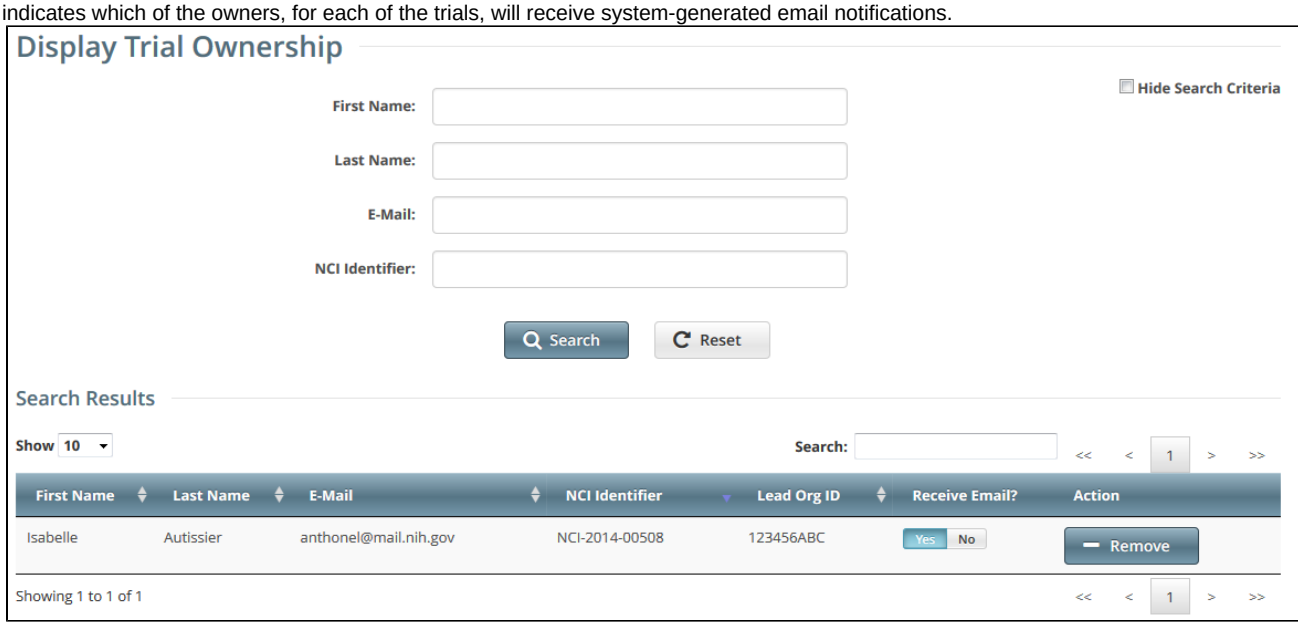
Displaying Trial Ownership

As a site administrator, you can display trial ownership for any trial owned by your site for which your organization or its family member organization is the lead organization. Trial owners can view trial details, update trials, and amend *Complete* trials. Additionally, you can indicate whether a user would like to receive system notifications, including TSRs and XML files, on a trial-by-trial basis.

> **TSR and XML distribution**
> Trial owners can access TSR and XML documents.

How to Display Trial Ownership

1. On the toolbar, click **Administration** > **Trial Ownership** > **View**.
   The Display Trial Ownership page displays the current owner(s) of the trials for which your organization is the lead organization. It also indicates which of the owners, for each of the trials, will receive system-generated email notifications.



2. To display all the trials owned by a given user, search for the user by first name, last name, or email address, and then click **Search**.
   All trials owned by the user are listed in the Search Results list.
3. To display all owners of a given trial, enter the NCI Identifier in the field provided, and then click **Search**.
   All owners of the selected trial are listed in the Search Results list.

You can filter the search results and create more space to display the results
To filter the search results, in the **Search** field, type one or more characters contained in any of the fields. The list is filtered as you type subsequent characters. For details, refer to Working with Tables and Search Results .

To create more space on the page, on the upper right corner of the page, select the **Hide Search Criteria** check box.

4. To indicate whether or not an owner of a trial should receive system-generated email messages, in the **Receive Email?** column, select **Yes** or **No**.

   Selecting **Yes** indicates that the owner will receive *all* notifications regarding the specified trial.

   Selecting **No** indicates that the owner will *not* receive any notifications regarding the specified trial.

5. To revoke ownership of a trial, locate the user/trial in the **Search Results** list, and then click **Remove**.

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Editing Trial Details

You can edit your updated trial details after you have reviewed them at any time before you submit them to the CTRP.

How to Edit Updated Details

1. Scroll to the bottom of the **Review Trial** Details page, and click **Edit**.

   The Update Trial page displays all information you have provided, in editable form.
2. Make changes as necessary and then follow the instructions in Reviewing and Submitting Trial Updates .

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Granting and Revoking Administrative Authority

The relationships between administrators and trials in a single organization are as follows:

- An organization can have the following:
  - One original site administrator
  - Many site administrators appointed by the original administrator
  - Many trials, providing that the organization plays the lead organization role
  - Many users affiliated with the site who can submit and own trials
- A trial can have the following:
  - One submitter
  - One organization affiliation, defined by the lead organization
  - Many trial owners

Site administrators are trial owners by default if the site administrator's affiliated organization is the trial's lead organization. A site administrator can be added explicitly as an owner of any trial. Refer to Managing Trial Ownership .

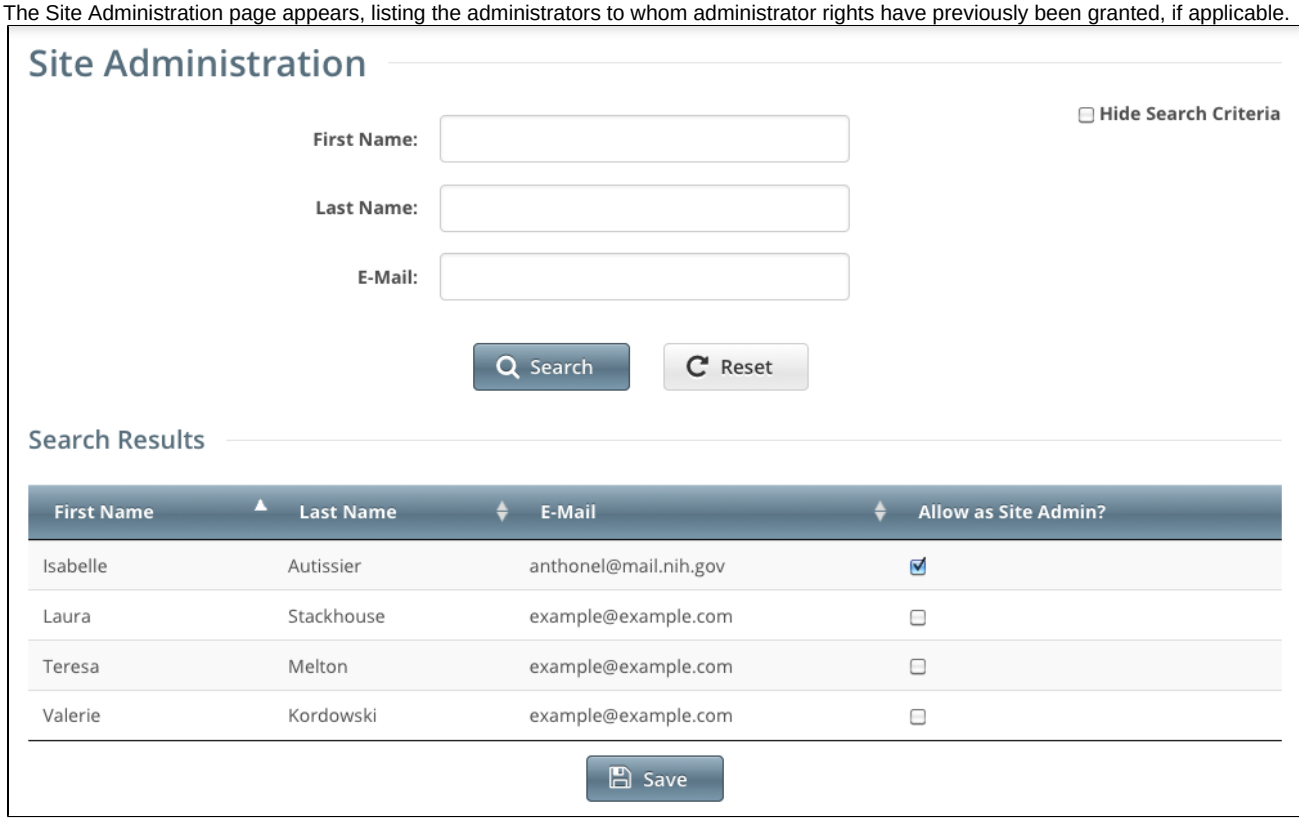
- A site administrator can do the following:
  - Display trial ownership
  - Manage trial ownership
  - Manage site record ownership
  - Manage Accrual access
  - Manage the administrative rights of other users in the organization
  - Revoke own administrative rights

Site administrators do not receive system-generated emails automatically
System-generated emails (including TSRs) are sent to a site administrator only if the site administrator's affiliated organization is the trial's lead organization, or if the site administrator is the trial submitter and/or trial owner. The site administrator can also manage email notification globally on the *My Account* page.

As a site site administrator, you can grant and revoke administrative rights to other users in your organization. (You can grant/revoke administrative authority to users who have a CTRP account and whose organizational affiliation is the same as your own.) Site administrators are the only Registration users who can see and access the Site Administration menu.

How to Grant and Revoke Site Administrator Rights

1. On the toolbar, click **Administration** > **Site Administration**.
   The Site Administration page appears, listing the administrators to whom administrator rights have previously been granted, if applicable.



2. Search for the Registration user for whom you want to adjust administrative rights: specify the user by first name, last name, or email address, and then click **Search**. The user's name appears in the Search Results list.
   a. To promote the user to site administrator, select the check box in the **Allow as Site Admin?** column.

      > As a site administrator you can revoke your own administrative rights. Use caution if you do so because you can not promote yourself thereafter.

   b. To revoke administrative access, clear the check box under the **Allow as Site Admin?** column.
3. Click **Save**.

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Managing Access to the Subject Accrual Application

Site Administrators can authorize users to submit subject accrual data for trials that have been fully abstracted and verified. Once assigned, users can submit accrual data for all trials associated with their affiliated organization or organization family members. For *Complete* trials (National, Externally Peer-Reviewed, or Institutional), the organization must be a lead; for *Abbreviated* trials (Industrial), the organization must be a participating site.

Assignment at the organization level pertains to trials that the organization has registered in CTRP and extends to those that it will register in the future. Similarly, assignment at the organization family level pertains to trials that any member organization has registered in CTRP and extends to those that it will register in the future.

Access to CTEP and DCP trial accruals is restricted to the CTRO only.

The table below outlines the access and trial assignment rules for *Complete* and *Abbreviated* trials.

Access/Assignment	Complete Trial	Abbreviated Trial
Who can assign access?	• A registered user logged in as the Lead Organization's Site Administrator for any trial other than DCP or CTEP trials • Super Abstractor for DCP and CTEP trials	• A registered user logged in as Site Administrator for any trial other than DCP or CTEP trials • Super Abstractor for DCP and CTEP trials
Who can be assigned access?	Any registered user affiliated with the Site Administrator's organization, or family member organization (including the Site Administrator)	Any registered user affiliated with the assigner's organization (including the site administrator)
What types of trials can be assigned?	Complete trials for which the assigner's organization is the lead organization	Abbreviated trials for which the assigner's organization is the Lead Organization or participating site
How is access assigned?	• By trial • By Organization • By Organization Family member The system automatically assigns the Organization Family Accrual Submitter access to any trial registered by new organizations added to an organization family in the future. It withdraws access if the Organization Family Accrual Submitter's organization is removed from the organization family in the future.	• By trial • By participating site
Who can submit accrual data?	Any assigned user, for any organization trials for which the assigner's organization is the Lead Organization	Any assigned user affiliated with the participating site
Which trials can the Organization Family Accrual Submitter submit accrual data to?	• All complete trials registered by the submitter's organization or family member organization • Trials currently registered in CTRP • Trials that the organization registers in CTRP in the future, once abstracted	• All abbreviated trials registered by the submitter's participating site *only* • Trials currently registered in CTRP • Trials that the organization registers in CTRP in the future, once abstracted

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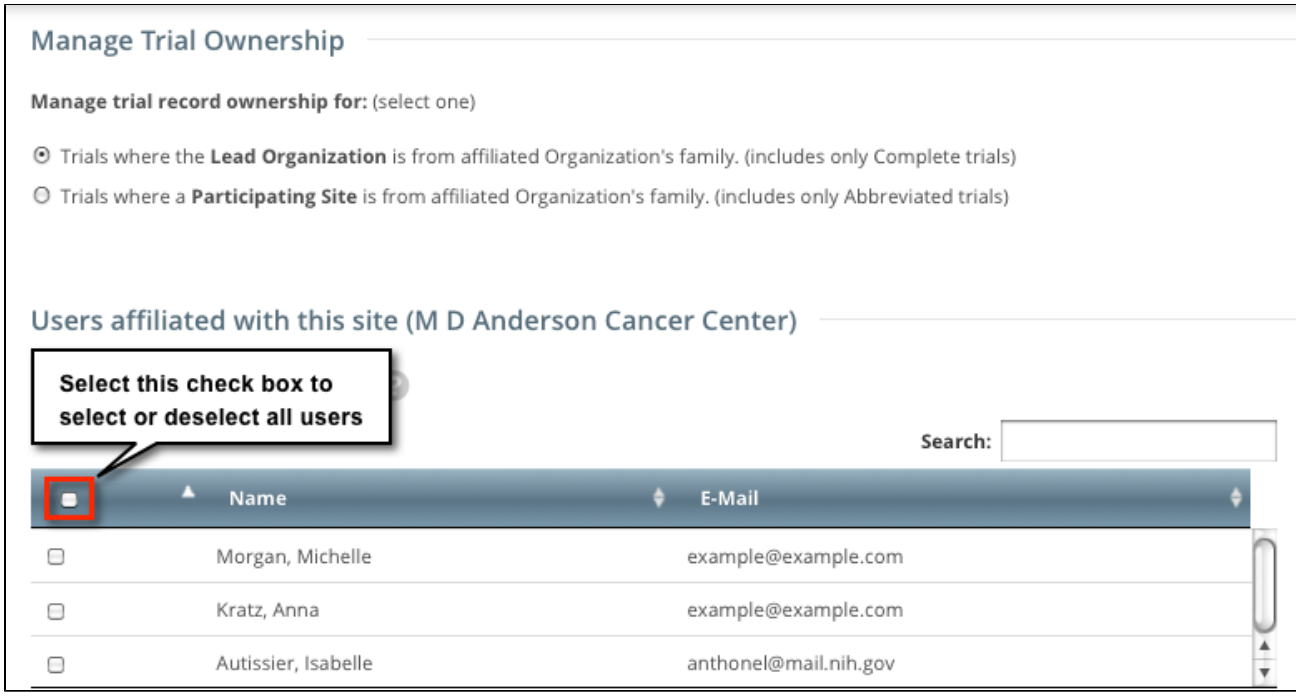
Managing Participating Site Record Ownership

How to Assign and Unassign Trial Ownership

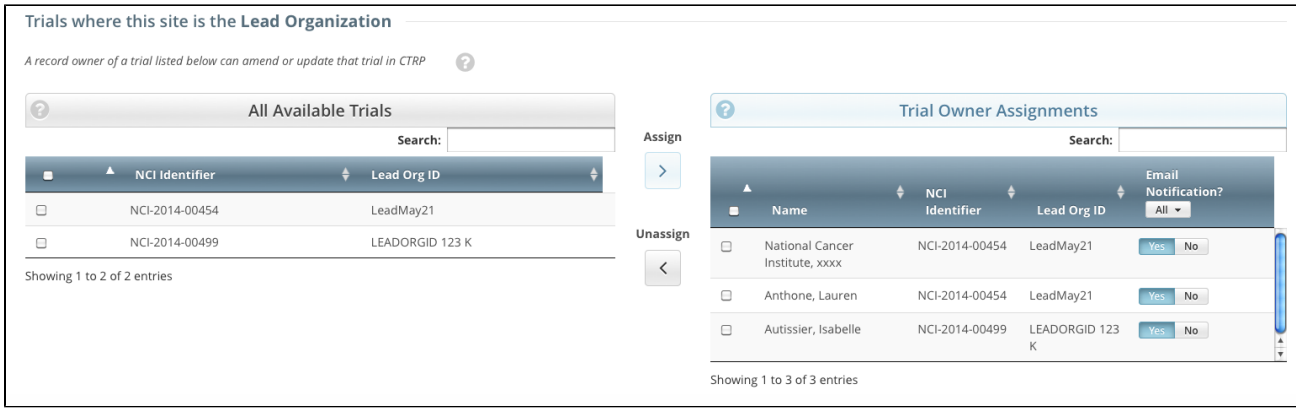
1. On the toolbar, click **Administration > Trial Ownership > Manage**.
   The Manage Trial Ownership page displays the names of your affiliated organization or it's family member organization(s) users on the top of the page, and trials that your organization owns as a Lead Organization or Participating Site below the list of names.



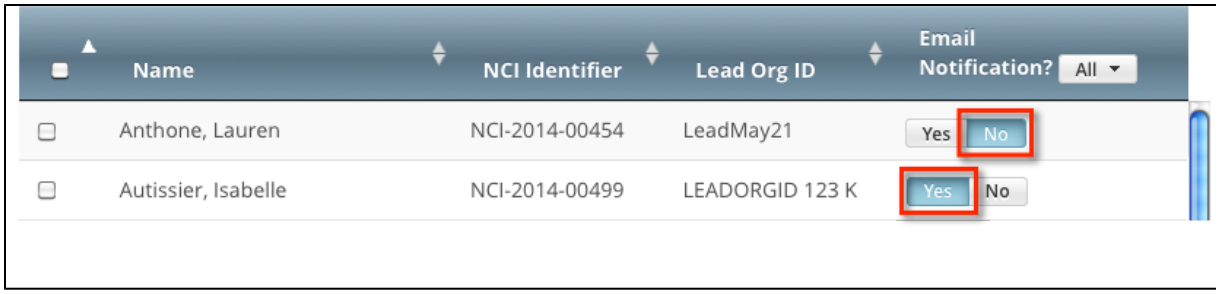
2. Under **Manage trial ownership for**, select which role your affiliated organization or its family member organization(s) play(s).
    a. For *Complete* trials, select **Lead Organization**.
    b. For *Abbreviated* trials, select **Participating Site**.
3. To indicate which users will have the ability to update and amend selected *Complete* trials; or update *Abbreviated* trials, select one or more user names on the list.

> **You can select or deselect all names, or filter the list of names**
> To select all names, select the check box on the left side of the column heading. Click it again to deselect all names.
>
> To filter the list of names, in the **Search** field, type one or more characters contained in a user's name or email address. The list is filtered as you type subsequent characters.

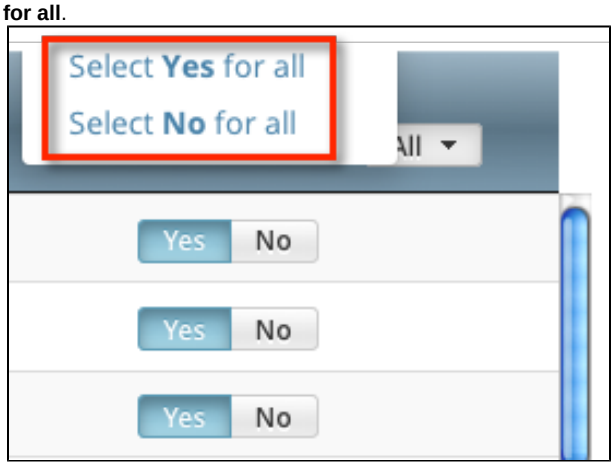
4. In the list of trials at the bottom of the page, under **All Available Trials**, or **All Abbreviated Trials**, select the trials to assign to the user(s), and then click the **Assign** icon (**>**).



5. To unassign trials, under **Trial Ownership Assignments**, or **Site Owner Assignments**, select the user(s) you want to unassign, and click the **Unassign** icon (**<**).
6. For *Complete* trials, indicate which trial owners should receive email notifications about the trial(s):
    - In the **Email Notifications?** column, click the **Yes** or **No** button.



- To indicate that all owners should receive/not receive email, in the **Email Notification** column header, click **All > Select Yes/No for all**.



> The **Select No for All** and **Select Yes for All** options apply globally to all trial owners, not just the ones currently visible in the list.

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Managing Program Codes

Each cancer center family uses program codes to group its clinical trials. As a site administrator, you can manage the set of program codes and program code assignments for your organization family. You can assign program codes to trials that meet all of the following criteria:

- Complete trials with a lead organization as a member of your cancer center family of organizations, or Abbreviated trials where such a member is a participant.
- Trials with status other than Withdrawn.
- Trials with processing status other than Rejected or Submission Terminated.
- Trials that were active during the cancer center reporting period.

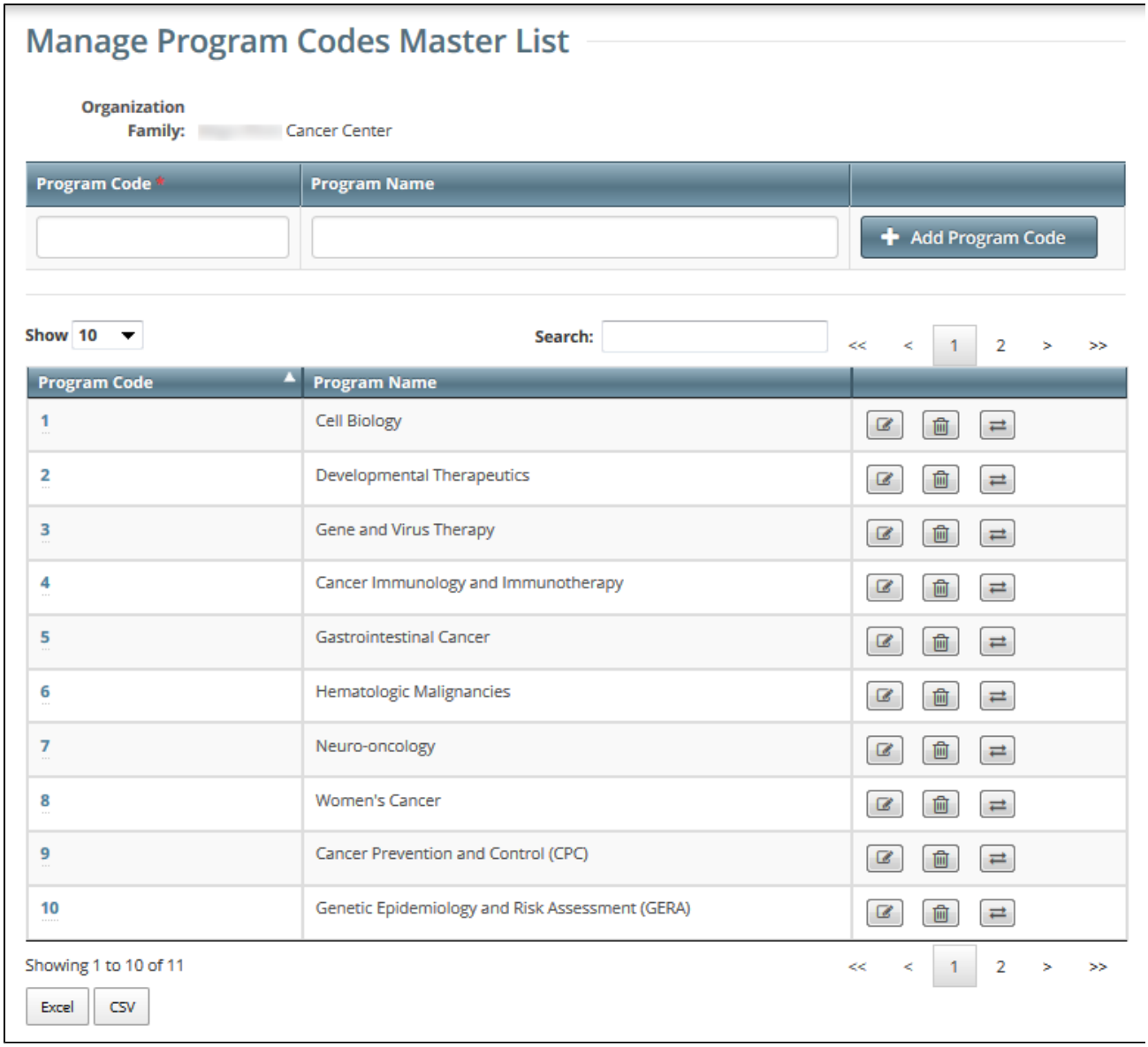
Keep in mind the following points about the entities in CTRP that represent NCI-designated Cancer Centers:

- A CTRP organization family represents an NCI-designated Cancer Center family of organizations. For brevity, this guide refers to this entity as a *Cancer Center family*, a *Cancer Center*, or an *organization family*.
- A CTRP organization that is a member of a Cancer Center family is considered a Cancer Center organization. For brevity, this guide refers to this entity as a *Cancer Center organization*.

Using the Manage Program Codes Master List Page

Viewing Program Codes

1. On the toolbar, click **Administration** > **Program Codes** > **Manage Master List**. The Manage Program Codes Master List appears.



2. Notice that this page displays information specific to your organization family.

You can navigate through the list of program codes just like any other list of search results in the CTRP Registration application. For instructions, refer to Working with Tables and Search Results.

Adding Program Codes

1. On the Manage Program Codes Master List page, in the **Program Code** field, enter a unique program code. This is likely to be a very short representation of the program.

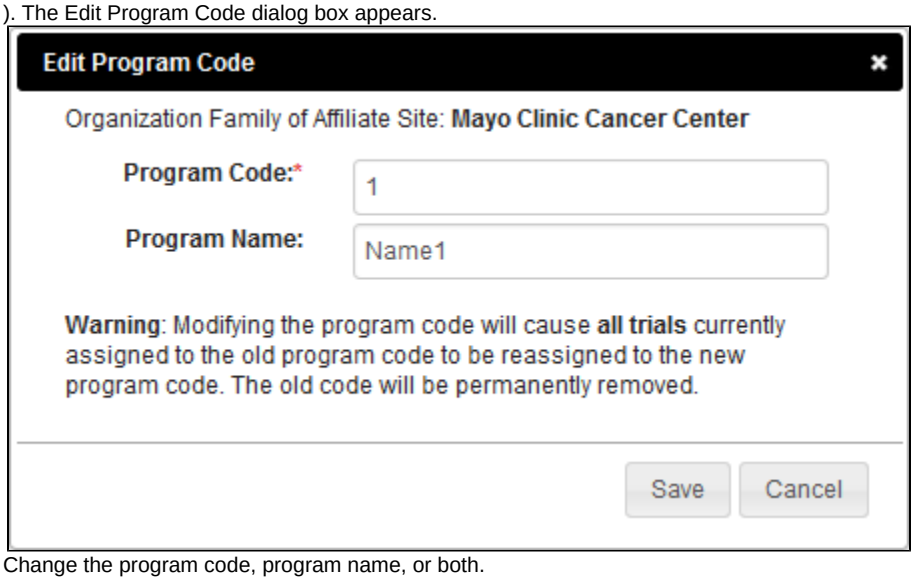
2. (Optional) In the **Program Name** field, enter a program name.
3. Click **Add Program Code**. The new program code appears in the list.

For each organization family, active program codes must be unique. The list may contain two entries with the same program code, if one is active and the other is inactive.

Editing Program Codes

When you change a program code, the system re-assigns to the new program code all trials (including closed trials) currently assigned to the old program code.

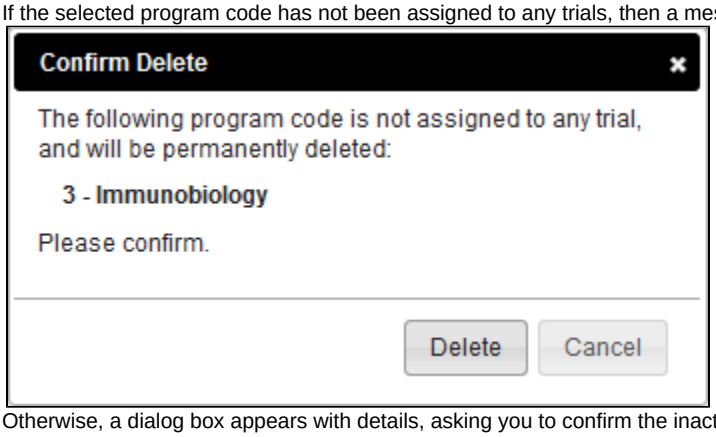
1. On the Manage Program Codes Master List page, in the row for the program code of interest, click the Edit icon ( ). The Edit Program Code dialog box appears.



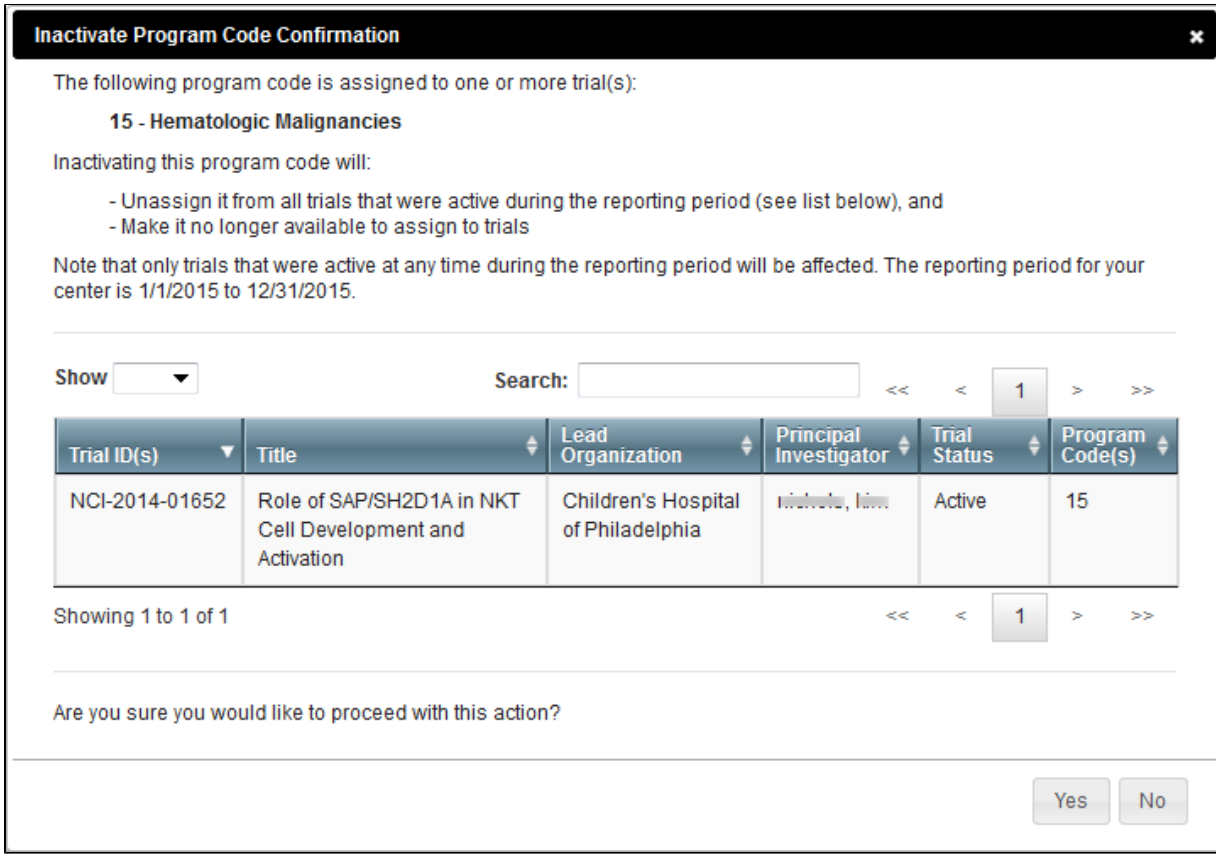
2. Change the program code, program name, or both.
3. Click **Save**.
    - If you have changed only the program name, the list reflects your change.
    - If you have changed the program code, a confirmation message appears. If you want to proceed, click **Yes**. The list reflects your change.

Deleting or Inactivating Program Codes

1. On the Manage Program Codes Master List page, in the row for the program code of interest, click the Delete icon ( ). The system checks whether the selected program code has been assigned to any trials. What happens next depends on the result of that system check:
    - If the selected program code has not been assigned to any trials, then a message appears, asking you to confirm the deletion.



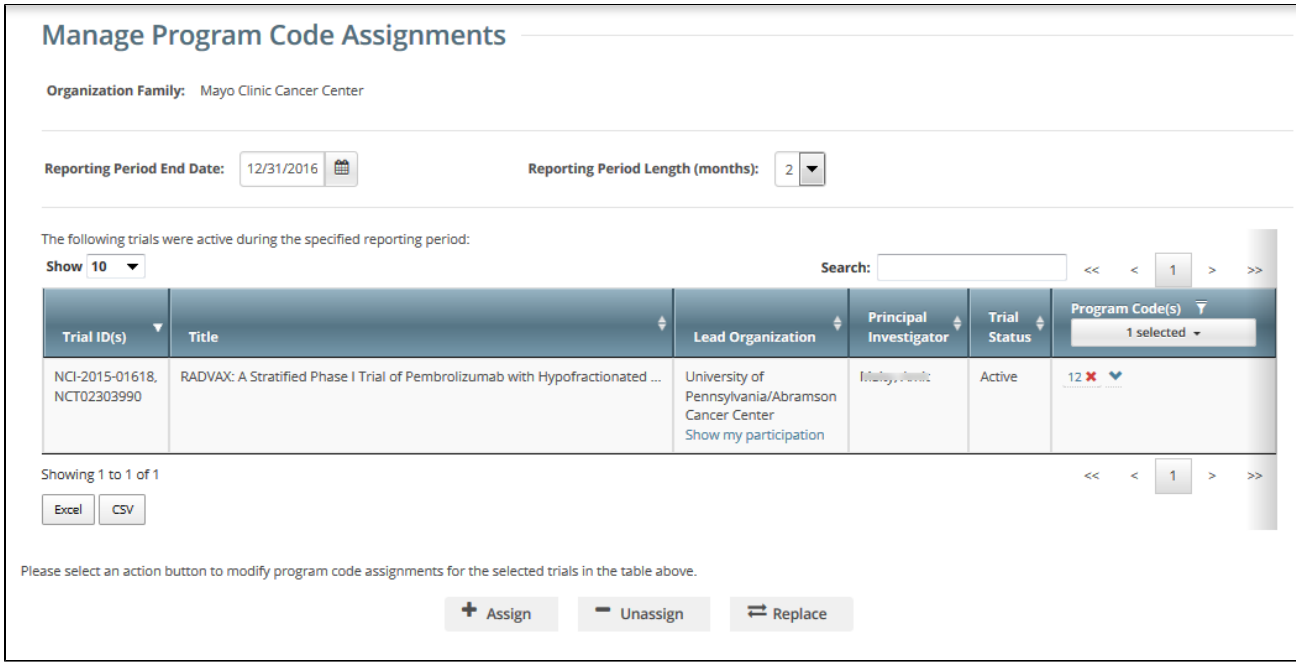
    - Otherwise, a dialog box appears with details, asking you to confirm the inactivation.



2. After reading the provided information, confirm or cancel the action:
    - To confirm deletion, click **Delete**. To confirm inactivation, click **Yes**. The list changes to reflect your action:
        - If you deleted a program code, the system removes the program code completely.
        - If you inactivated a program code, the system removes the program code from *only* trials that were active at any time during the reporting period. The program code remains in the Master List with "-inactive" appended, but you can no longer assign it to trials.
    - To cancel deletion, click **Cancel**. To cancel inactivation, click **No**.

Viewing the Assignments for a Program Code

1. On the Manage Program Codes Master List page, in the row for the program code of interest, click the View icon (). The Manage Program Code Assignments page appears.



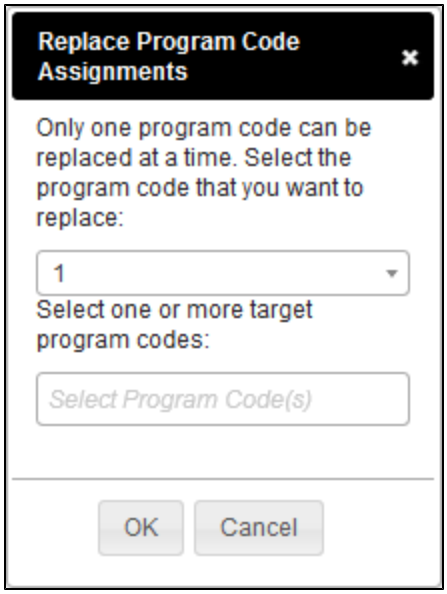
2. Notice that this page displays information specific to a date range:
    - The default end date is 12/31/2015. In the **Reporting Period End Date** field, consider specifying a different date.
    - The default reporting period length is 12 months. In the **Reporting Period Length** field, consider specifying a different number.
3. Notice that this page displays a list of trials that meet all the following criteria:
    - Trials in which any member of your organization family is a participant.
    - Trials assigned the program code that you selected on the Manage Program Codes Master List page.
    - Trials with any of the following statuses at any time within the reporting period, as specified on this page:
        - In Review
        - Approved
        - Active
        - Enrolling by Invitation
        - Temporarily Closed to Accrual
        - Temporarily Closed to Accrual and Interventions
4. If you want to filter the list, click the filter icon (
    
) in the Program Code(s) column. The Select Program Code(s) button appears. Click **Select Program Code(s)**. The list includes all program codes and other options. Select one or more program codes from the list. (To select all program codes or deselect all program codes, toggle the **Select/Deselect All** option. To display trials that have not been assigned to program codes, select **None**.) The system updates the list of trials to reflect your selections.

You can navigate through the list of trials just like any other list of search results in the CTRP Registration application. For instructions, refer to Working with Tables and Search Results. On the Program Code Assignments page, in the search box, if you include the search term in double quote marks (for example "cancer"), the search results include trials that have an exact match in any of the first five columns.

Using the Manage Program Code Assignments Page

Replacing a Program Code

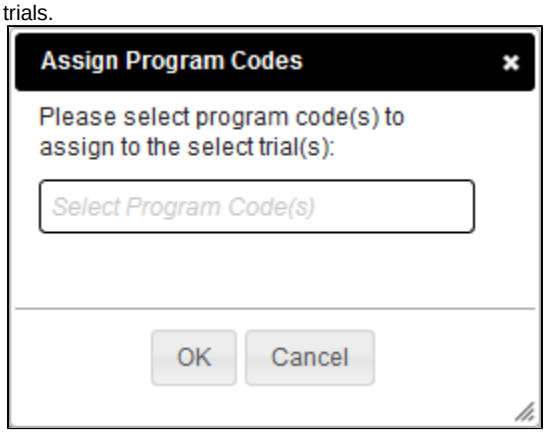
1. On the Manage Program Code Assignments page, select one or more trials that have been assigned to program codes.
2. Click **Replace**. The Replace Program Code Assignments dialog box appears with two lists. The first list includes all program codes assigned to any selected trial.



3. In the first list, select the program code that you want to replace.
   The second list includes all program codes for the organization family. However, the one you selected in the first list becomes unavailable for selection in the second list.
4. In the second list, select one or more target program codes.
5. Click **Replace**. On the Manage Program Code Assignments page, the Program Code(s) column reflects your changes.

Assigning Program Codes to Multiple Trials

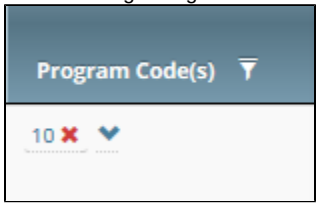
1. On the Manage Program Code Assignments page, select one or more trials of interest.
2. Click **Assign**. The Assign Program Codes dialog box appears. The list includes all program codes that can be assigned to the selected trials.



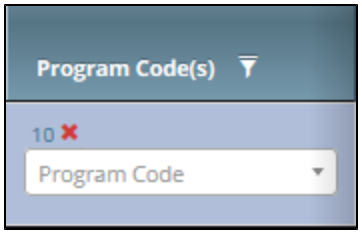
3. In the list, select one or more target program codes.
4. Click **Assign**. On the Manage Program Code Assignments page, the Program Code(s) column reflects your changes.

Assigning a Program Code to a Single Trial

1. On the Manage Program Code Assignments page, in the row for the trial of interest, in the **Program Code(s)** column, click the v icon.



   The Program Code field appears.



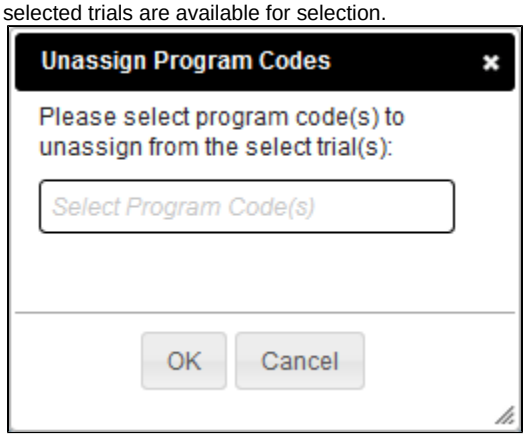
2. Click the **Program Code** field. The list includes all program codes, but the ones already assigned to the selected trial are unavailable for selection.
3. Select the target program code. On the Manage Program Code Assignments page, the Program Code(s) column reflects your changes.

You can also assign a program code to a trial while performing the following tasks:

- Registering, amending, or updating a Complete trial. For instructions, refer to Registering New Trials, specifically Recording Data Table 4 Information.
- Adding your site after importing a trial. For instructions, refer to Registering Abbreviated (Industrial and Other) Trials.
- Adding a participating site to an Abbreviated trial or updating such a site (as a site affiliate). For instructions, refer to Adding Your Site to Abbreviated Trials.
- Adding participating sites to Abbreviated trials (as a site administrator). For instructions, refer to Adding Sites.

Unassigning Program Codes from Multiple Trials

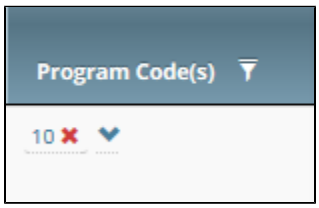
1. On the Manage Program Code Assignments page, select one or more trials that have been assigned to program codes.
2. Click **Unassign**. The Unassign Program Codes dialog box appears with a list of all program codes, but only the ones assigned to the selected trials are available for selection.



3. In the list, select one or more program codes.
4. Click **Unassign**. On the Manage Program Code Assignments page, the Program Code(s) column reflects your changes.

Unassigning a Program Code from a Single Trial

On the Manage Program Code Assignments page, in the row for the trial of interest, in the **Program Code(s)** column, click the **x** for the program code you want to unassign. The Program Code(s) column reflects your changes.

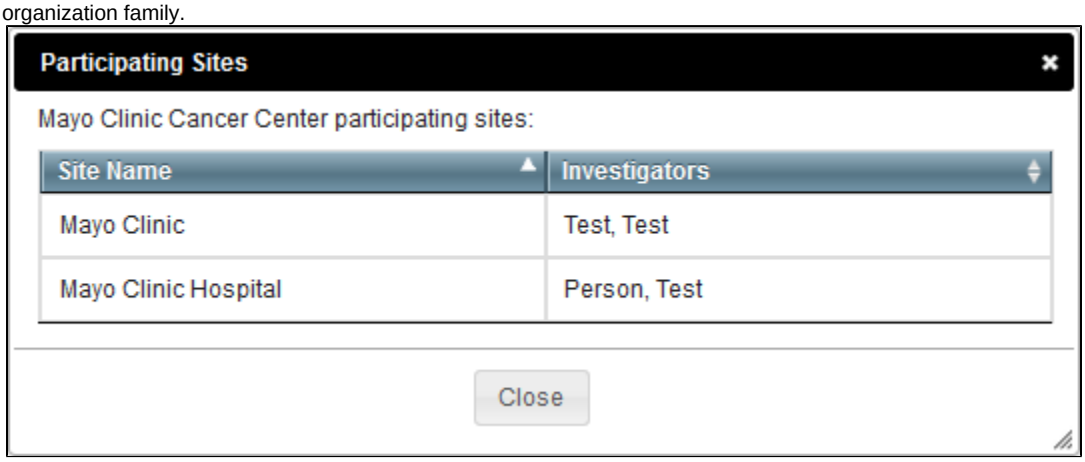


You can also unassign a program code to a trial while performing the following tasks:

- Amending or updating a Complete trial. For instructions, refer to Registering New Trials, specifically Recording Data Table 4 Information.
- Adding a participating site to an Abbreviated trial or updating such a site (as a site affiliate). For instructions, refer to Adding Your Site to Abbreviated Trials.
- Adding participating sites to Abbreviated trials (as a site administrator). For instructions, refer to Adding Sites.

Viewing Your Participation

1. On the Manage Program Code Assignments page, in the row for the trial of interest, in the **Lead Organization** column, click **Show my participation**. The Participating Sites dialog box appears, listing only the participating organizations that are members of your organization family.



2. When you are done viewing the list of participating sites, click **Close**.

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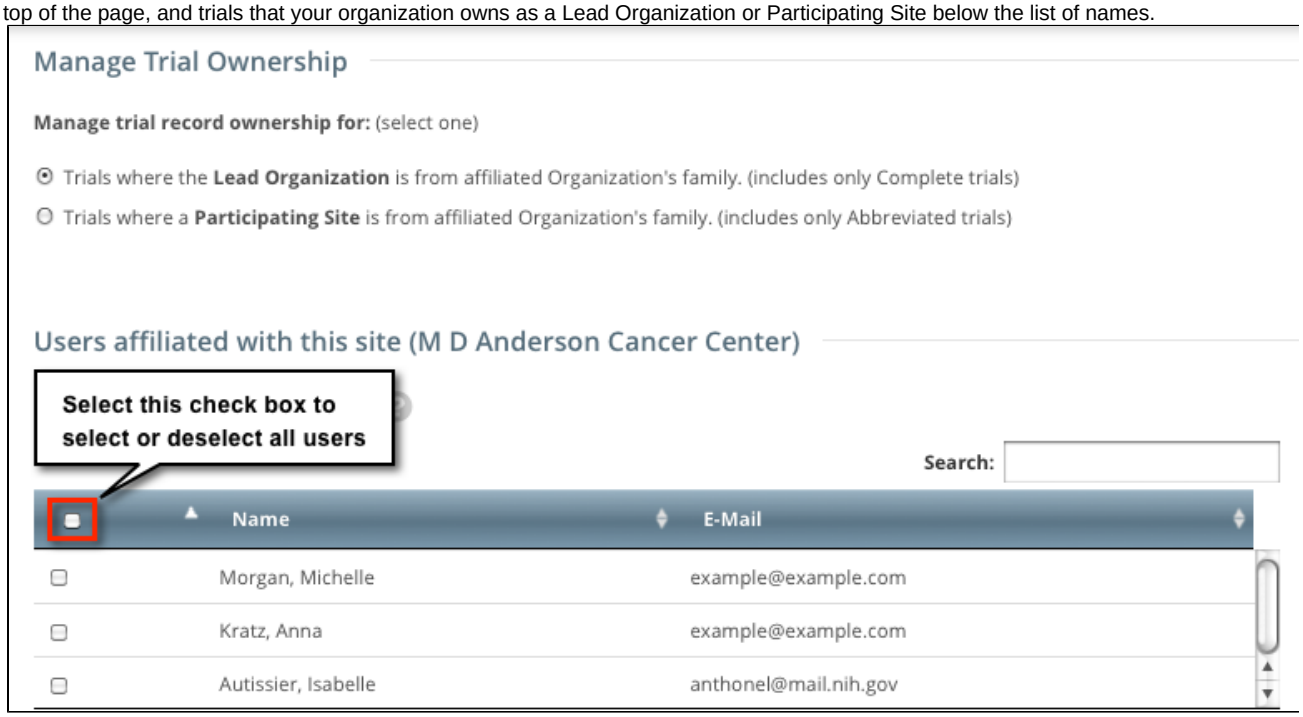
Managing Trial Ownership

How to Assign and Unassign Trial Ownership

1. On the toolbar, click **Administration > Trial Ownership > Manage**.
   The Manage Trial Ownership page displays the names of your affiliated organization or it's family member organization(s) users on the top of the page, and trials that your organization owns as a Lead Organization or Participating Site below the list of names.

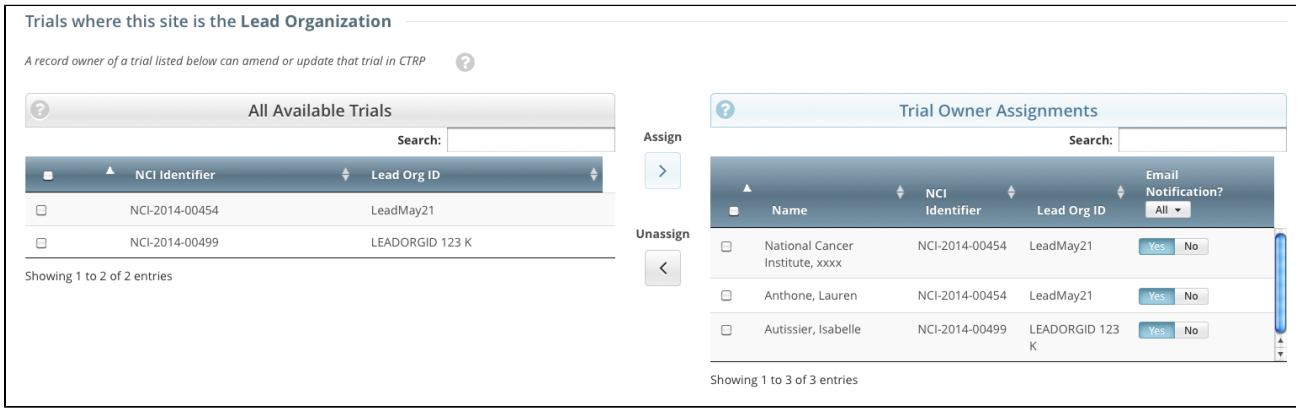


2. Under **Manage trial ownership for**, select which role your affiliated organization or its family member organization(s) play(s).
   a. For *Complete* trials, select **Lead Organization**.
   b. For *Abbreviated* trials, select **Participating Site**.
3. To indicate which users will have the ability to update and amend selected *Complete* trials; or update *Abbreviated* trials, select one or more user names on the list.

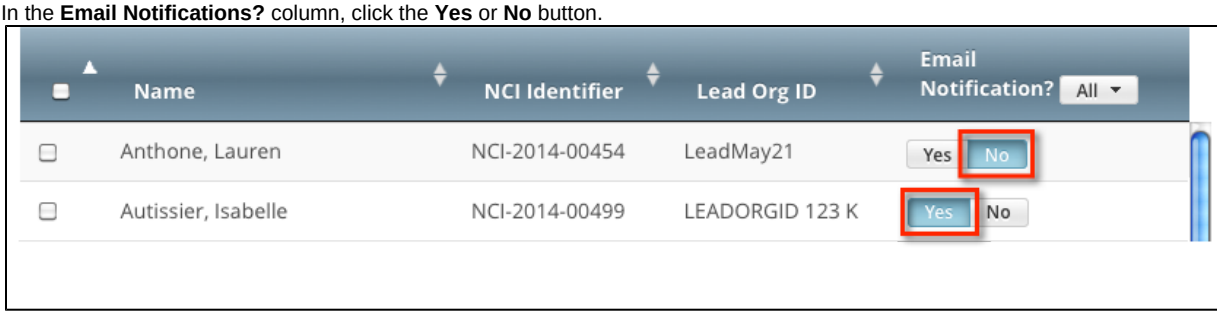
You can select or deselect all names, or filter the list of names
To select all names, select the check box on the left side of the column heading. Click it again to deselect all names.

To filter the list of names, in the **Search** field, type one or more characters contained in a user's name or email address. The list is filtered as you type subsequent characters.

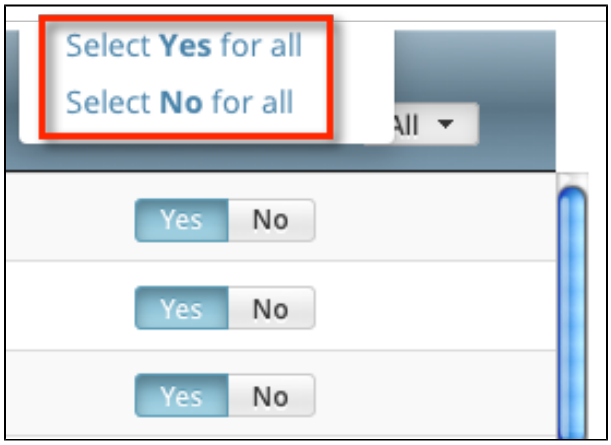
4. In the list of trials at the bottom of the page, under **All Available Trials**, or **All Abbreviated Trials**, select the trials to assign to the user(s), and then click the **Assign** icon (**>**).



5. To unassign trials, under **Trial Ownership Assignments**, or **Site Owner Assignments**, select the user(s) you want to unassign, and click the **Unassign** icon (**<**).
6. For *Complete* trials, indicate which trial owners should receive email notifications about the trial(s):
   - In the **Email Notifications?** column, click the **Yes** or **No** button.



   - To indicate that all owners should receive/not receive email, in the **Email Notification** column header, click **All > Select Yes/No for all**.



The **Select No for All** and **Select Yes for All** options apply globally to all trial owners, not just the ones currently visible in the list.

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Managing Who Can View Reports

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Managing Your Account

You can update your account information after you have registered for an account and have logged in to Registration.

> **Changing your Organizational Affiliation results in loss of privileges**
> If you change your organizational affiliation, the system revokes your existing Site Admin and Accrual Submission privileges.

How to Edit Your Account Information

1. On the top right corner of any page, click **Your Username > My Account.**
   The My Account page appears, populated with the information you previously supplied for your account.
2. In the **Your Account Profile** section, make any changes as necessary, and then click **Save**.

> **Keep your account up to date**
> The PRS organization name is required for uploading trial records to ClinicalTrials.gov via a system-generated file. The PRS organization name you include in your profile is included in that file. This precludes having to update the PRS name in the file. Therefore it is very important for you to update your account whenever there is a change in PRS.

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Registering Industrial and Other Trials

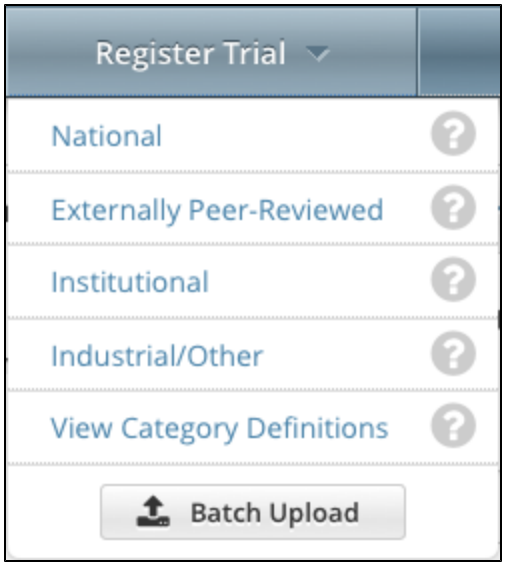
You can register Industrial/Other trials in the CTRP by importing them directly from ClinicalTrials.gov. You must enter a ClinicalTrials.gov Identifier (NCT ID) for each trial you register. If the trial you want to register does not have an NCI ID, or if you do not know it, contact the CTRO for assistance at ncictro@mail.nih.gov.

> The system registers the trials you import from ClinicalTrials.gov as *Abbreviated* trials. To classify a trial as "Other", contact the Clinical Trials Reporting Office staff at ncictro@mail.nih.gov after importing/registering the trial in the CTRP system.
>
> For more information about Data Table 4 categorization, see Guidelines for Abbreviated Trials.

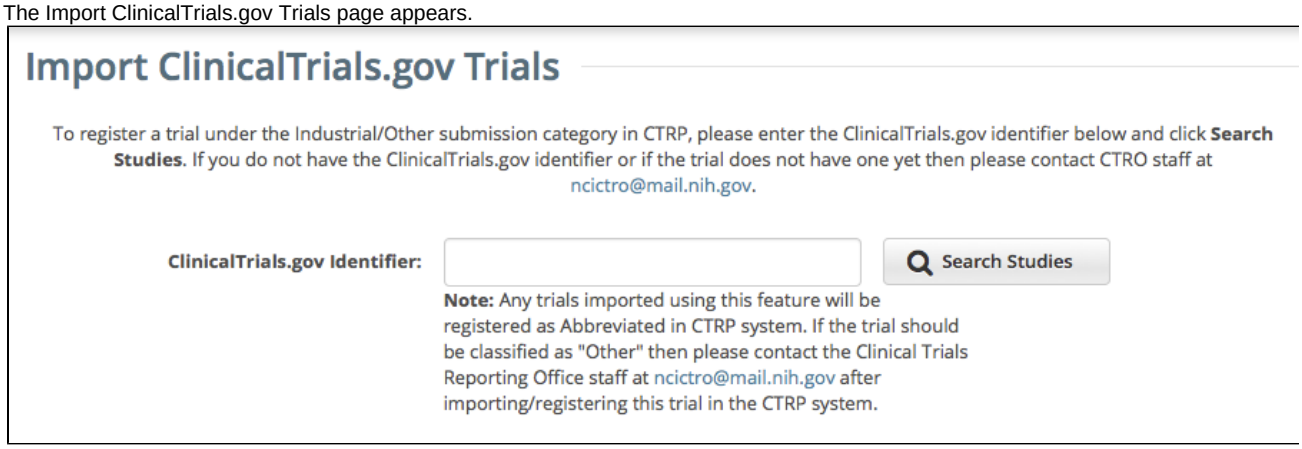
How to Register Industrial Trials

1. On the toolbar, click **Register Trial**, and select **Industrial/Other**.

> To read a definition of each of the trial submission categories (study sources), click **View Trial Category Definitions**, or, click the Help icon (
>
>
>
>) next to each category.

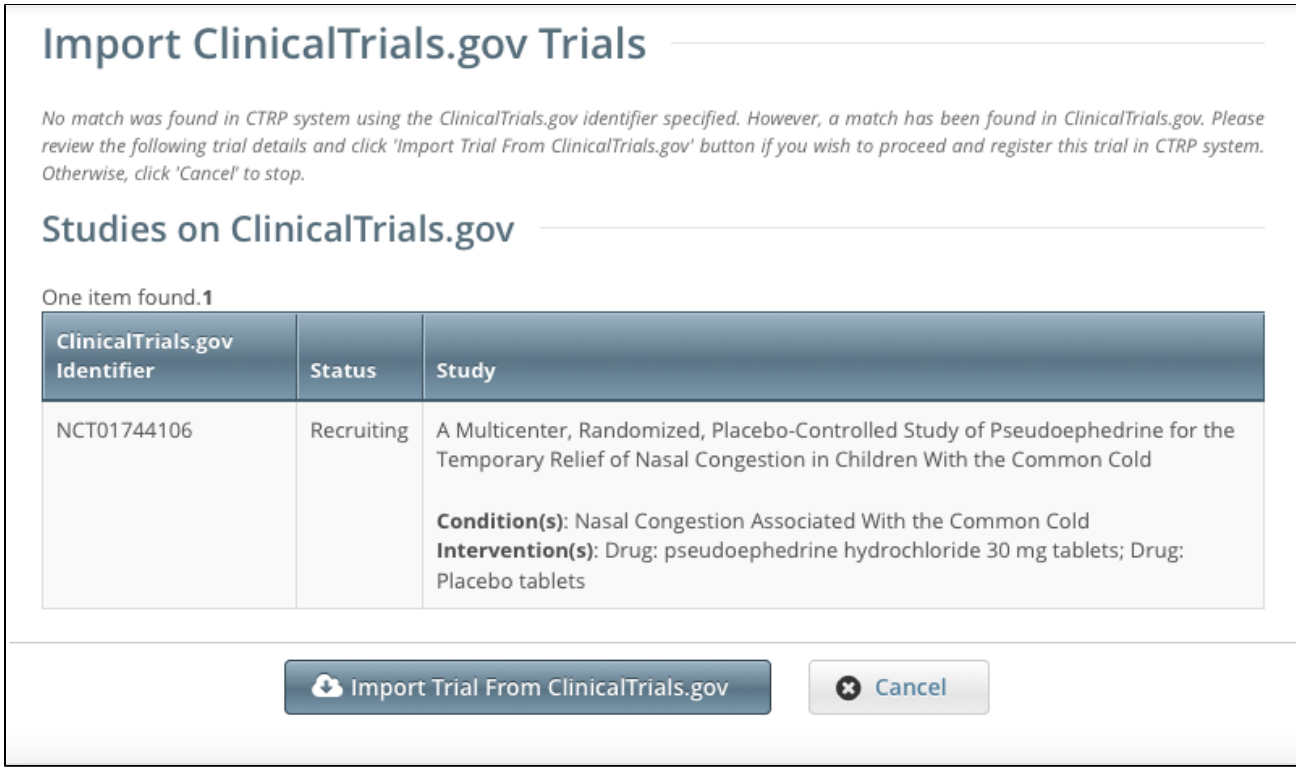


The Import ClinicalTrials.gov Trials page appears.



2. Enter the ClinicalTrials.gov Identifier, and then click **Search Studies**.

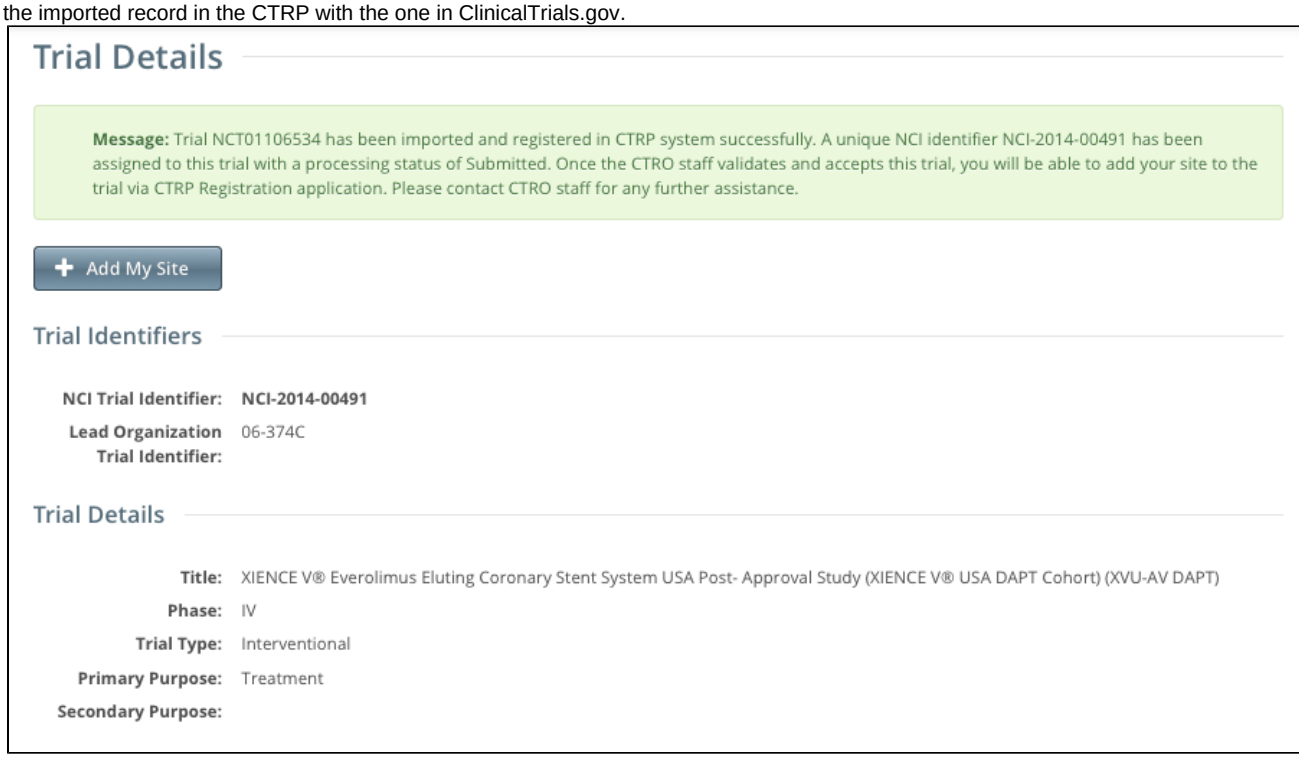
   The system searches for the ID you entered. If it finds a match in the CTRP, you can not import the trial.
3. If the system does not find a match in the CTRP, the trial record from ClinicalTrials.gov appears.



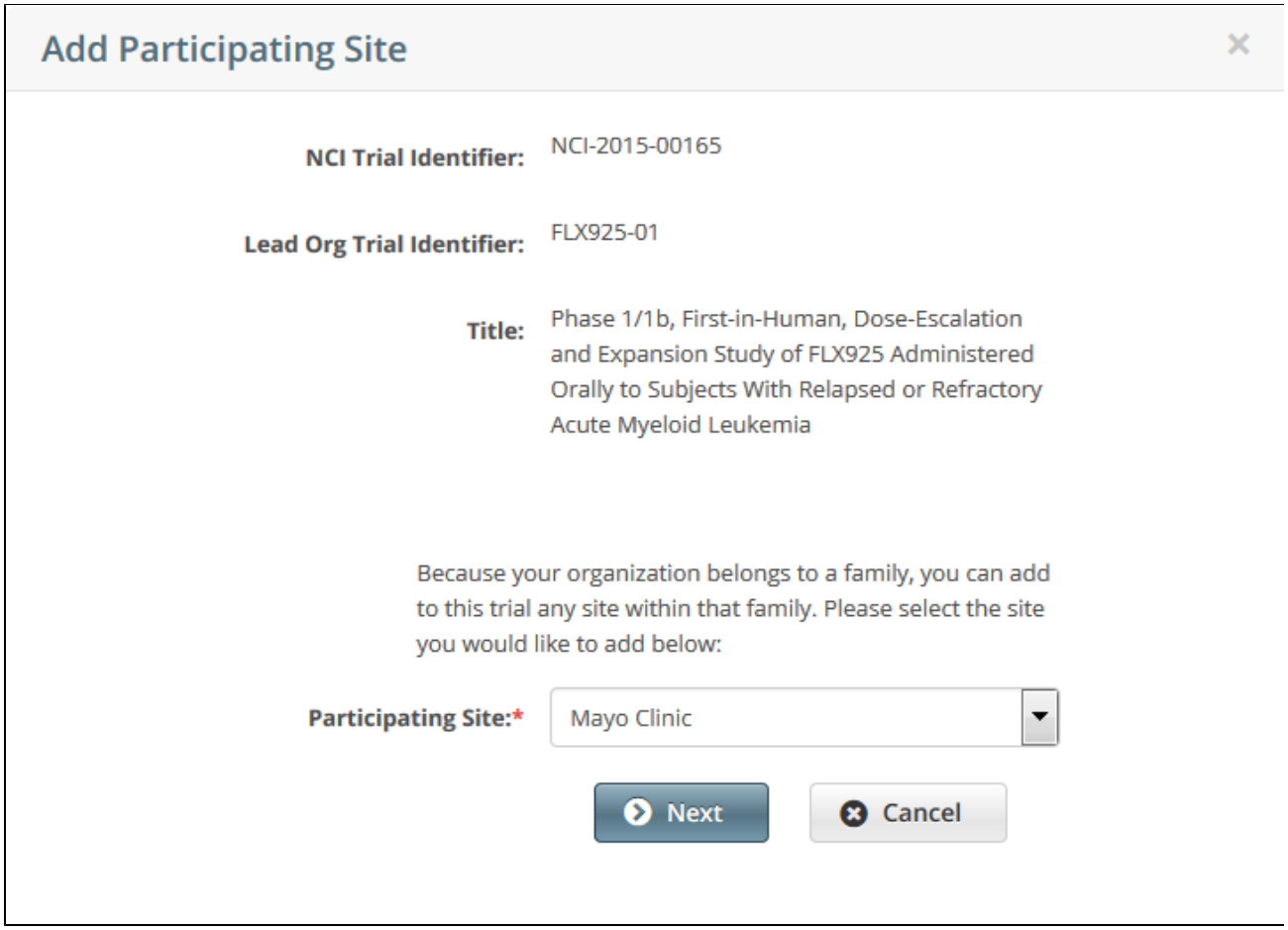
4. Click **Import Trial From ClinicalTrials.gov**.

> While it is possible for two users to attempt to import a trial at the exact same time, the system cannot process simultaneous imports. If you receive an error message the first time you attempt to import a trial, wait a short while, and then try again.

The trial is registered in the CTRP and assigned a unique NCI identifier with the processing status Submitted. The system synchronizes the imported record in the CTRP with the one in ClinicalTrials.gov.

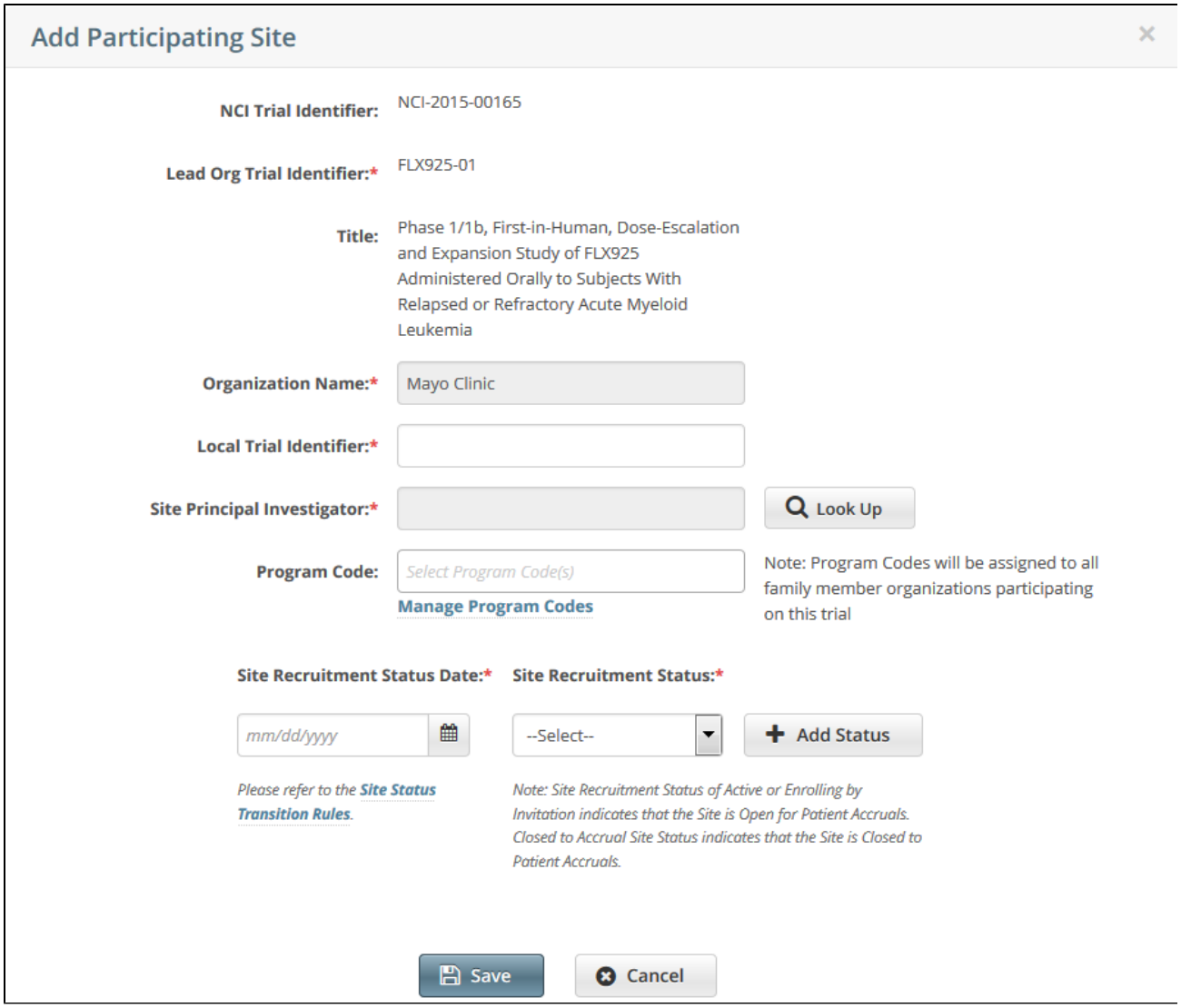


5. To add your site as a participant in the trial, click **Add My Site**. The Add Participating Site page appears.



The Participating Site list contains all organizations in the Organization Family associated with your CTRP account.

6. From the **Participating Site** list, select the organization that you want to add to this trial. Click **Next**. Another Add Participating Site page appears.



7. Complete the fields as per the instructions in Adding Your Site to Abbreviated Trials, and then click **Save**.

   The system sends you an email message when the CTRO has accepted the trial for registration in the CTRP. If your trial is not *Industrial*, contact the CTRO at ncictro@mail.nih.gov to request categorization of the trial as either *National* or *Externally Peer-Reviewed*.

The system synchronizes *Industrial* and *Other* trials currently registered in the CTRP with ClinicalTrials.gov trials every night by comparing their ClinicalTrials.gov Identifiers. The system updates CTRP trial records with the data imported from ClinicalTrials.gov if it finds matching records.

> The CTRP system does not import Person information from ClinicalTrials.gov.

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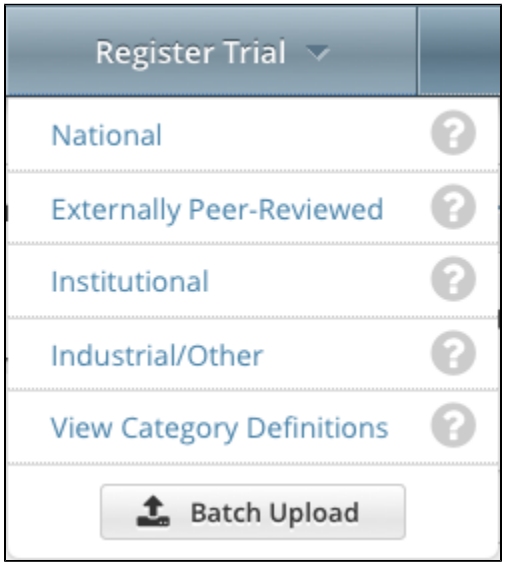
Registering New Trials

> Before you begin to register a trial, ensure that the trial does not exist in the system already by searching for trials using any of the criteria as per the instructions in Searching for Trials . The system uses the Lead Organization ID, Lead Organization Trial ID, and the ClinicalTrials.gov Identifier to detect duplicates. If a duplicate is detected, the system will not record your trial.

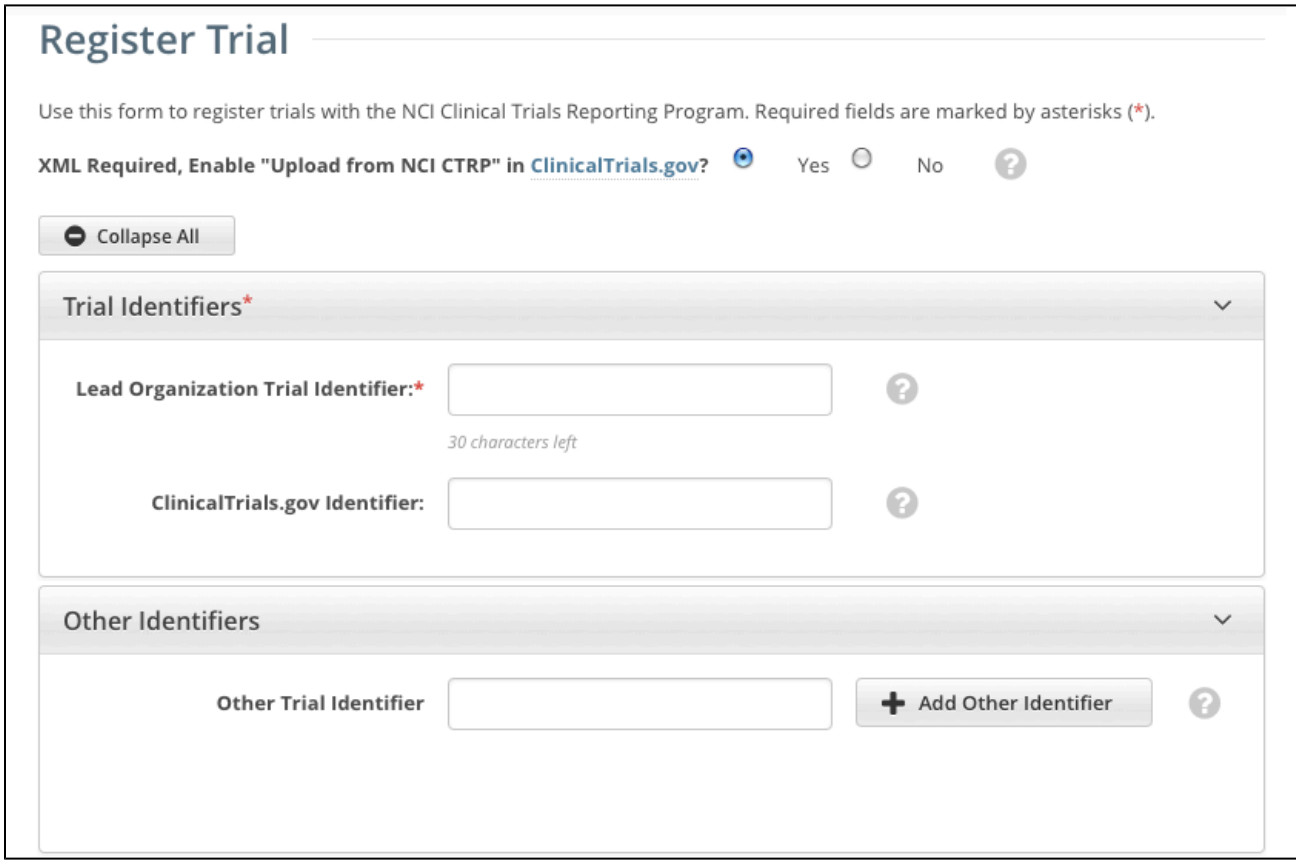
How to Register New Complete Trials

1. On the toolbar, click **Register Trial**, and select your trial's Submission Category (funding source) from the drop-down list, either **National**, **Externally Peer-Reviewed**, or **Institutional**.

> To read a definition of each of the trial submission categories (study sources), click **View Trial Category Definitions**, click the Help icon (
>
>) next to each category, or refer to http://cancercenters.cancer.gov/GrantsFunding/DataGuide#dt4.



The Register Trial page appears.



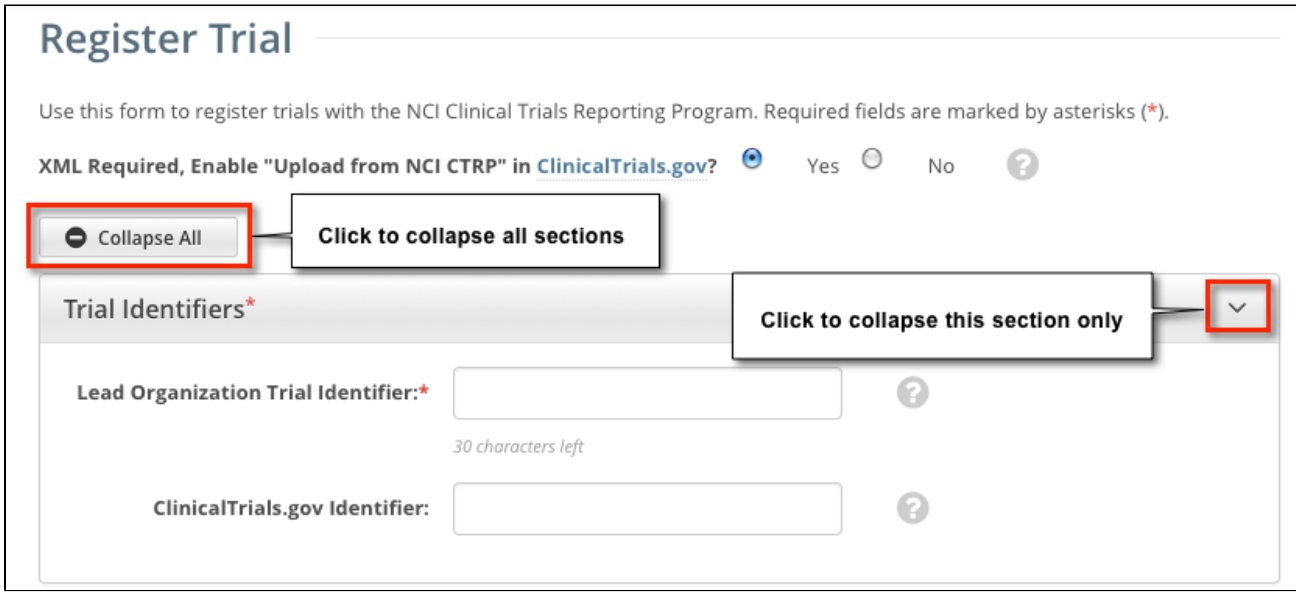
The system can create an XML document that is formatted to facilitate trial registration with ClinicalTrials.gov. The document it creates contains all the information that you submit during registration and all the trial data abstracted by the CTRO. If you indicate that you do

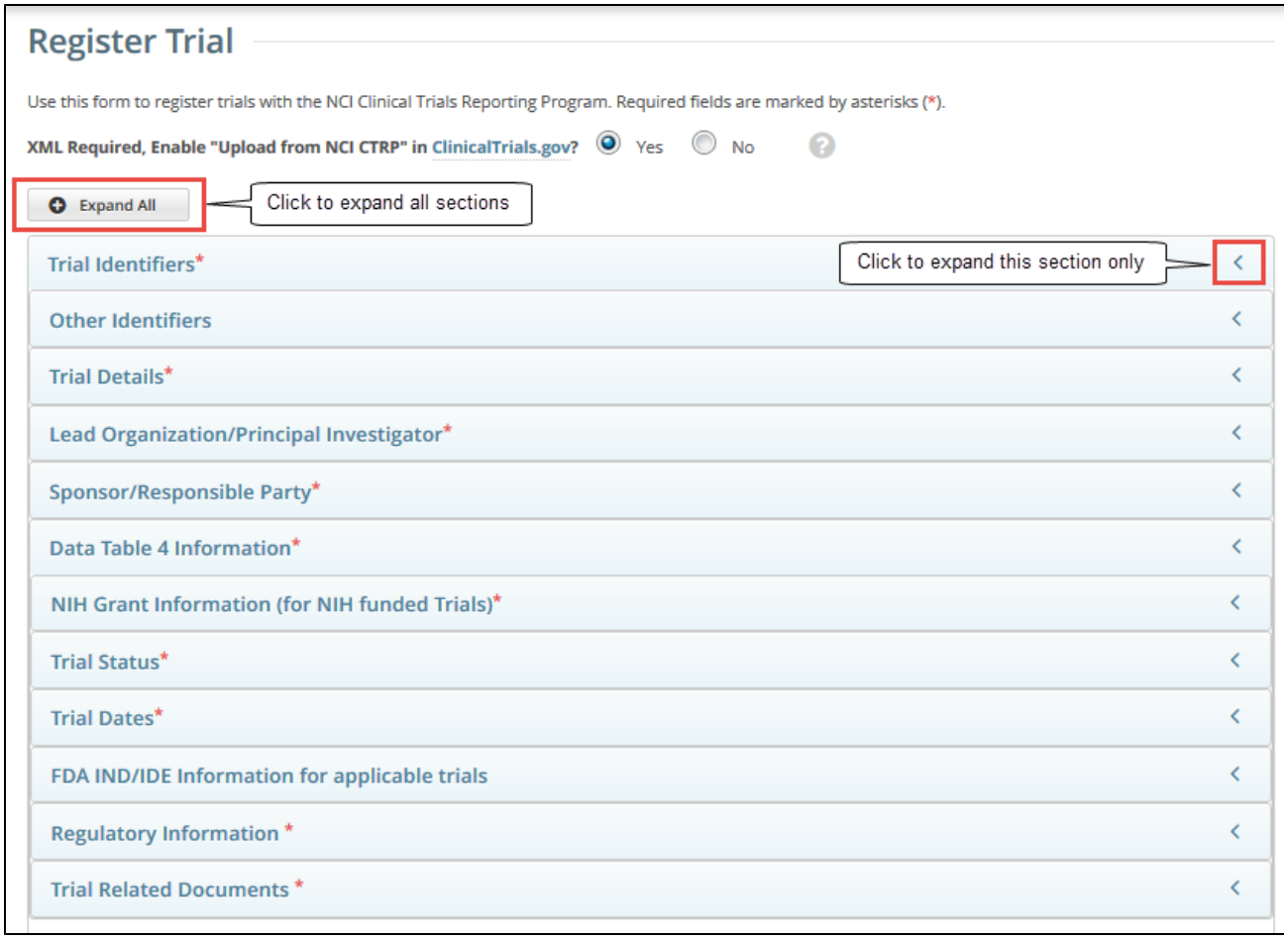
not need to register the trial with ClinicalTrials.gov, you will not be asked to provide regulatory and responsible party information.

You can expand and collapse sections of the registration page
By default, all sections of the registration form are displayed.

To collapse or expand each section individually, click the **Collapse** or **Expand** icon on the right side of the section title as shown in the figures below.

To collapse all sections, click **Collapse All**.





2. Select or enter the appropriate information in the text fields and drop-down lists. Fields are described in the following table.

> **Tip**
> Be sure to provide information for all fields marked with an asterisk (*). If you cannot complete the registration of a trial in one Registration session, you can save a draft of the trial details you have completed. Later you can return to complete the registration in another session.

Instructions for registering Complete *trials*

XML required. Enable "Upload from NCI CTRP" in ClinicalTrials.gov?	If you require an XML document to register your trial with ClinicalTrials.gov, select **Yes**. If you are not going to submit your trial to ClinicalTrials.gov, select **No**. The option you select here dictates which sections you will be required to complete. For example, if you select **No**, you will not be required to complete responsible party and regulatory information. If you select **Yes**, NCI will be added as a collaborator to the Funding Source.

Various	Select or enter the appropriate information in the text fields and drop-down lists as appropriate according to the detailed instructions provided for each of the following sections: a. Recording Trial Identification Information b. Recording Interventional Trial Details c. Recording Non-interventional Trial Details d. Recording Lead Organizations and Principal Investigators e. Recording Sponsors and Responsible Parties f. Recording Data Table 4 Information g. Recording NIH Grants h. Recording Trial Statuses i. Recording Trial Dates j. Recording INDs and IDEs k. Recording Regulatory Information l. Recording Trial-Related Documents
Save as Draft	Click to save a draft of the record so that you can complete the registration at another time. You must have provided, at the minimum, both the Lead Organization and Lead Organization Trial Identifier to save a draft. The system saves your draft, assigns it a unique ID (for tracking purposes), and sends you an email message confirming that the information has been saved. You can end your Registration session and retrieve your draft later to complete the registration.
Review Trial	Click to initiate the system check for errors and missing information. The system displays the results in a message at the top of the Review Trial Details page. Indicators mark specific fields that you must complete or correct in order to submit the trial. The Review Trial Details page is read-only. To make changes to the trial data, follow the instructions in Recording Interventional Trial Details and Recording Non-Interventional Trial Details .
Cancel	Click to cancel the registration. A pop-up message prompts you to confirm cancellation. If you choose to cancel the registration, you will lose all data that you may have entered.

3. Correct any errors if indicated, and repeat the previous steps as many times as necessary until the trial is error-free.
4. To continue with the trial registration, scroll to the bottom of the **Review Trial Details** page, and then click **Submit**. To prevent creating a duplicate record, do not click **Submit** more than once. If you have to make changes after you click **Submit**, contact the CTRO at ncictro@mail.nih.gov rather than using your browser's Back button to make changes.
   The registration notification message system sends you an email message to acknowledge that the trial has been submitted. Later it sends another email message to notify you when your trial has been accepted or rejected.

After submission, most users other than the trial submitter can not see the trial information you provided until the information has been validated. However, an organization administrator (if one exists) and an assigned owner can access the information prior to validation.

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Searching for Organizations

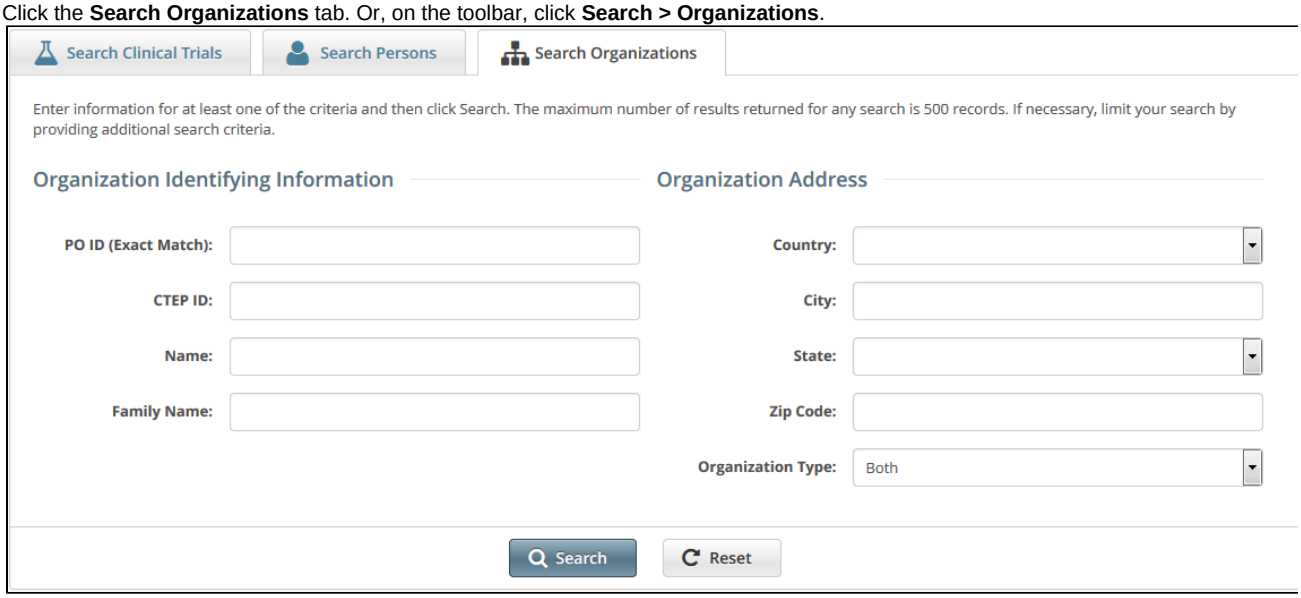
You can search for organizations that are currently registered with the Clinical Trials Reporting Program by any of the following criteria:

- Organization Identifying Information
  - **PO ID** - Enter the exact PO ID only
  - **CTEP ID** - Enter all or part of the CTEP ID
  - **Name** - Enter all or part of the Organization's name
  - **Family Name**. Enter all or part of the Organization Family's name
- Organization Address
  - **Country** - Select the country from the drop-down list
  - **City** - Enter all or part of the organization's primary location
  - **State** - Select the state from the drop-down list
  - **Zip Code** - Enter all or part of the Zip code

- Organization Type. Select one of the following:
  - **Lead Organization** - Returns organizations that are Lead Organizations
  - **Participating Site** - Returns organizations that are Participating Sites
  - **Both** - Returns organizations that are *either* Lead Organizations *or* Participating Sites

How to Search for Registered Organizations

1. Click the **Search Organizations** tab. Or, on the toolbar, click **Search > Organizations**.



2. Provide as much information as you can about the organization you are looking for, or, enter the Person/Organization (PO) ID or Cancer Therapy Evaluation Program (CTEP) Identifier. You must enter search criteria in at least one field.

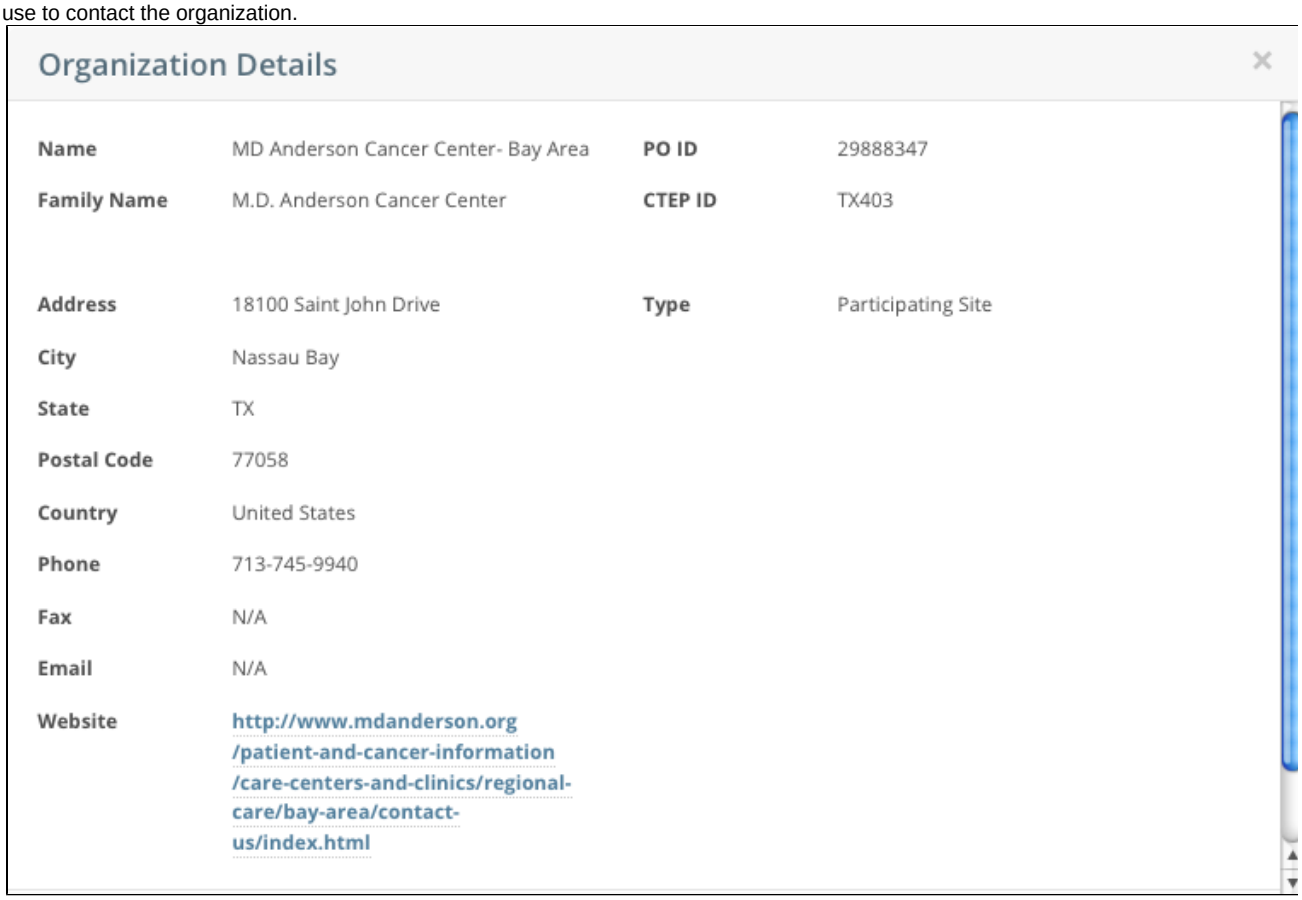
> **Searching by PO ID**
> The PO ID you enter for your search criterion must be exact and complete. That is, do not use partial IDs or wildcards.

> **Using wildcard characters (%)**
> You can enter a series of characters in any of the search fields (except the PO ID, which must be an exact match) to narrow the search results.The system adds wildcards on both sides of the search string (the series of letters you type) for you implicitly. You can type wildcard symbols (% or *) between characters of the string as necessary.

3. Click **Search**.
The organizations that meet your search criteria are listed in the Search Results table. To navigate the search results table, see Working with Tables and Search Results.

Tip
If the organization you are searching for is not listed, you may have searched too narrowly (that is, you may have provided too much information about the organization). If the list of results is very long and contains many organizations that are similar to the one you are searching for, you can narrow your search by providing more information.

4. If the organization does not appear in the results table, do one of the following to modify your search:
   - To broaden your search so that more organizations are listed in the search results, delete one or more of your criteria. For example, if you searched by part of the organization's name, city, state, and zip code in your original search, you may want to search by state alone.
     - or -
   - To narrow your search so that fewer organizations are listed in the search results, provide more about your organization. For example, if you searched by state in your original search, you may want to search by city in addition to the state.
5. To view the details of any organization in the search results list, click its **PO-ID**.
   The Organization Details window displays current information about the organization, including a live web and/or email link that you can use to contact the organization.



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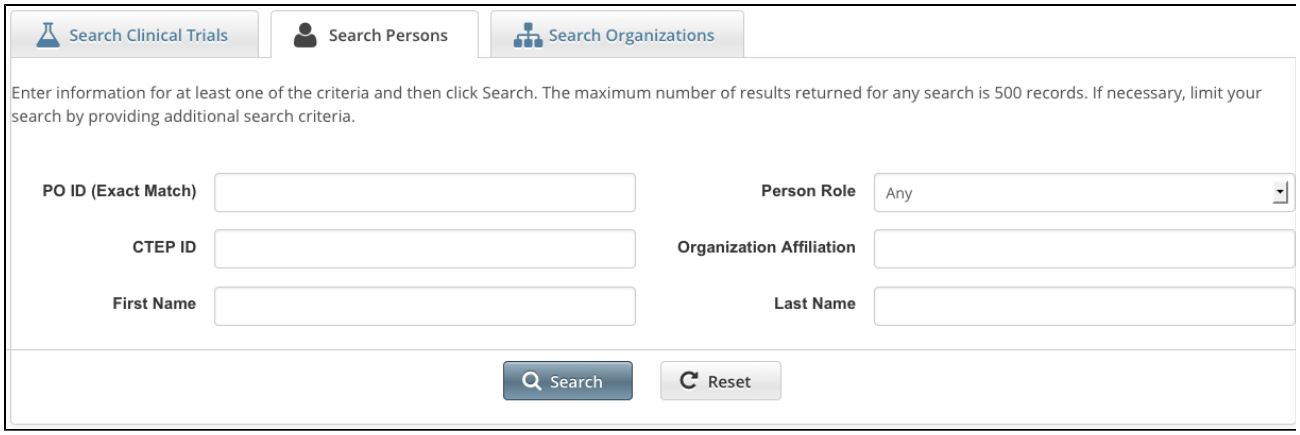
Searching for Persons

You can search for persons that are currently registered with the Clinical Trials Reporting Program.

How to Search for Registered Persons

1. Click the **Search Persons** tab. Or, on the toolbar, click **Search > Persons**.

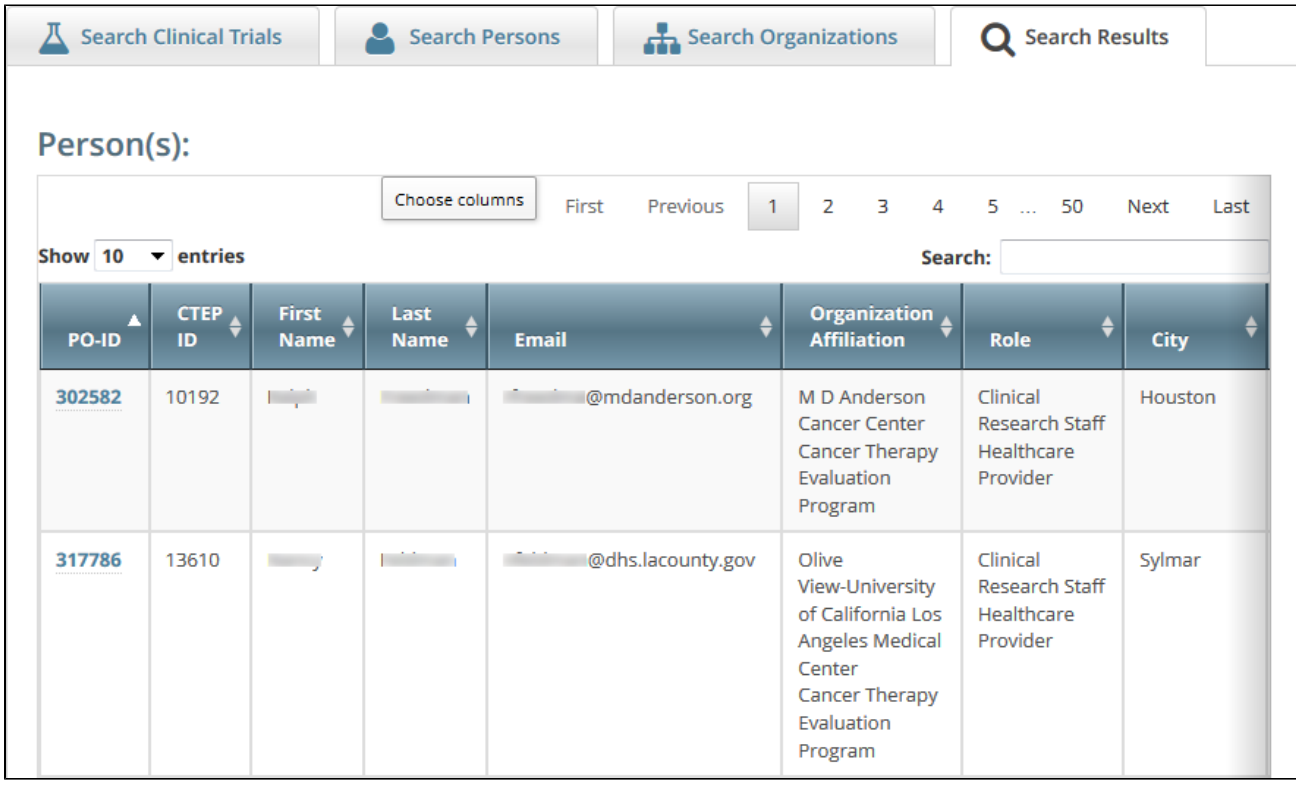


2. Provide as much information as you can about the person you are looking for, or, enter the Person/Organization (PO) ID or Cancer Therapy Evaluation Program (CTEP) Identifier. To search by person role, select a role from the **Person Role** drop-down list. You must enter search criteria in at least one field.

> **Searching by PO ID**
> The PO ID you enter for your search criterion must be exact and complete. That is, do not use partial IDs or wildcards.

> **Using wildcard characters (%)**
> You can enter a series of characters in any of the search fields (except the PO ID, which must be an exact match) to narrow the search results.

3. Click **Search**.
The persons that meet your search criteria are listed in the Search Results table. To navigate the search results table, see Working with Tables and Search Results.

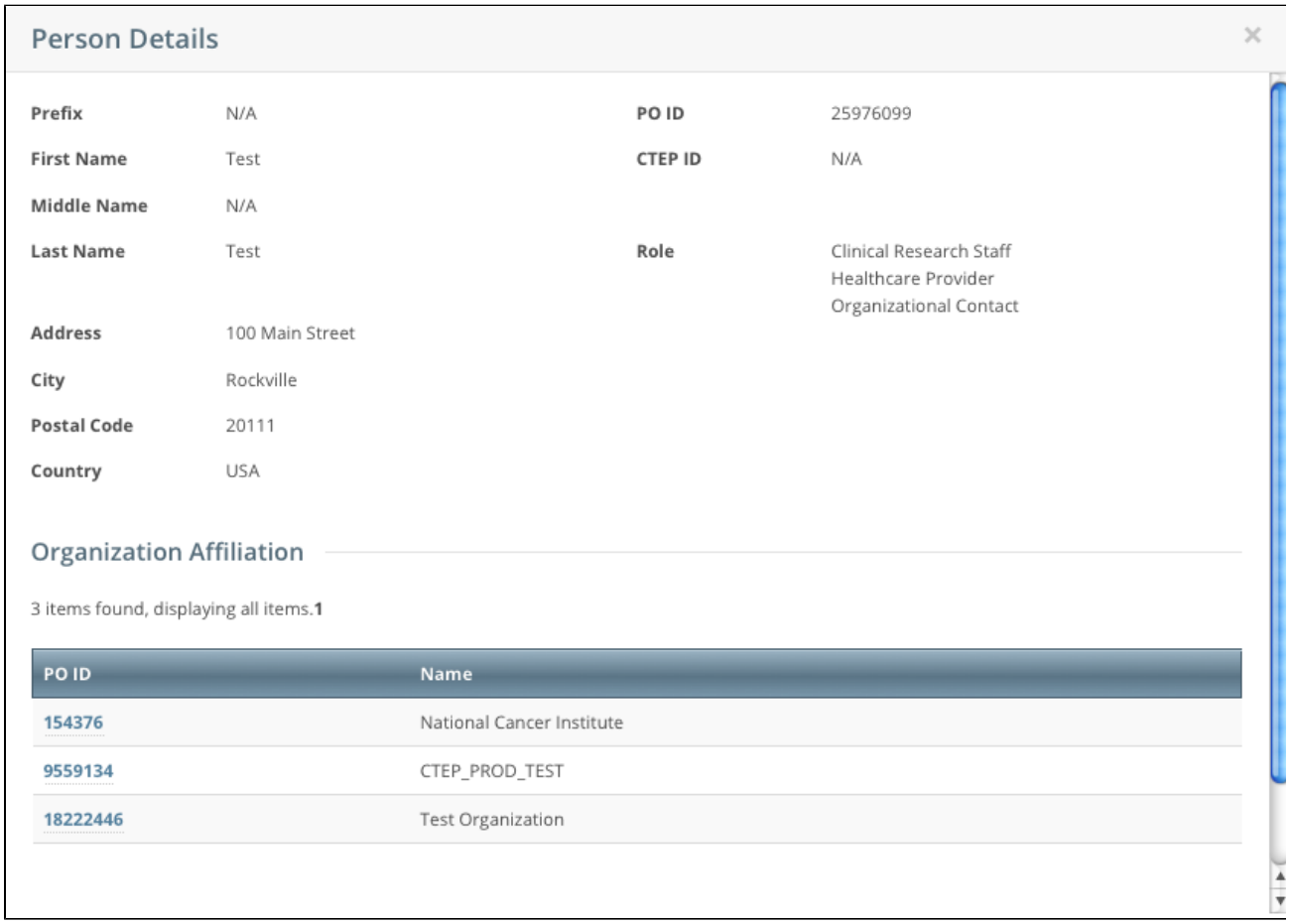


> **Tip**
> If the person you are searching for is not listed, you may have searched too narrowly (that is, you may have provided too much information about the person). If the list of results is very long and contains many persons that are similar to the one you are searching for, you can narrow your search by providing more information.

4. If the person does not appear in the results table, do one of the following to modify your search:

- To broaden your search so that more persons are listed in the search results, delete one or more of your criteria. For example, if you searched by part of the person's name, city, state, and zip code in your original search, you may want to search by state alone.
  - or -
- To narrow your search so that fewer persons are listed in the search results, provide more about your person. For example, if you searched by state in your original search, you may want to search by city in addition to the state.

5. To view the details of any person in the search results list, click its **PO-ID** link.
   The Person Details window displays current information about the person.



6. To view the details of the organization with which the person is affiliated, click its **PO-ID** link.

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Searching for Trials

You can retrieve existing trial records once you have registered for an account. See Creating CTRP Accounts.

After you have selected your search criteria, you can further limit or expand your search for trials as follows:

- Use the **Search All Trials** feature to search for all trials registered with the CTRP from all organizations/accounts, whether or not you are the submitter or owner.
- Use the **Search My Trials** feature to search for trials that you own, whether or not your organization is listed as the lead organization or participating site.
- Use the **Search Saved Drafts** feature to search for trials that you have saved as drafts but have not submitted.

The search feature you choose determines which categories of trials will be returned, and the actions you can perform with those results, as shown in the table below. See Working with Search Results for rules that determine which trial details are displayed.

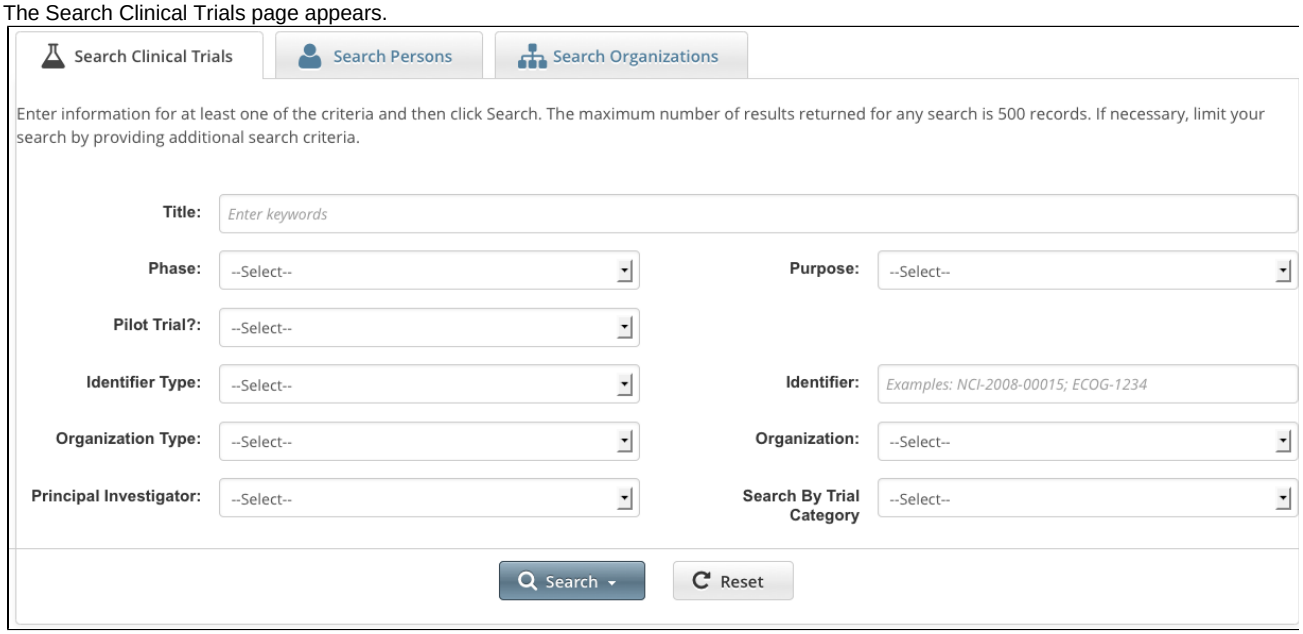
Search Option	Search All Trials	Search My Trials	Search Saved Drafts

Types of Trials Returned	All trials	• Trials you own that are on hold • Trials you own, including those conducted at an affiliated site.	Partial Submissions
Actions Permitted	• View Trial Details • Add/Update My Site (Abbreviated trials only) • Verify Trials (for trials you submitted but may not own) The results of this search may include a subset of trials that you own or submitted.	• View Trial Details • Update Trials • Amend Trials • Request TSR/XML • Change Status • Add/Update My Site (Abbreviated trials only) • Verify Trials	• View Trial Details • Complete Submissions • Add/Update My Site (Abbreviated trials only)

All registered users can search trials with the "Accepted" and subsequent processing status. Additionally, you can search for trials that you own that have not been validated. These trials are indicated by the "Submitted" status. See Trial Processing Statuses for information about statuses that occur during the course of the trial processing workflow.

How to Search for Existing Trials

1. Click the **Search Clinical Trials** tab. Or, on the toolbar, click **Search > Clinical Trials**.
   The Search Clinical Trials page appears.



2. Select or enter the appropriate information in the drop-down lists and text fields. (You do not have to select or enter any search criteria if you use the **Search My Trials** feature. When searching **All Trials**, you must select or enter at least one search criterion.) The following table describes the fields.

> **Tip**
> If you are searching for a saved draft, search by **Phase**, **Purpose**, or **Title** only. Because the system adds wildcards for you, do not enter wildcard symbols in the search fields.

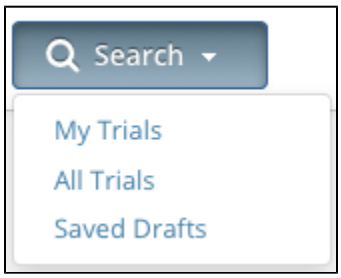
Trial Search Criteria

To search by this...	*Do this...*
Title	Enter one or more words from the long title or name of the trial provided by the principal investigator or sponsor. **Avoid copying and pasting, or typing the entire title into the search field** Use keywords rather than phrases or the entire title. Doing so minimizes the potential for excluding from the search results any titles with misspellings or slightly different phrasing.

Phase	Select the trial phase from the drop-down menu. Valid values are as follows: • **0** - Exploratory trials, involving very limited human exposure, with no therapeutic or diagnostic intent (e.g., screening studies, micro dose studies). See FDA guidance on exploratory IND studies for more information. • **I** - Includes initial studies to determine the metabolism and pharmacologic actions of a medical approach in humans, the side effects associated with increasing doses or exposure, and to gain early evidence of effectiveness; may include healthy participants and/or patients. • **I/II** - Includes trials that are a combination of phases I and II. • **II** - Includes controlled clinical studies conducted to evaluate the effectiveness of the medical approach for a particular indication or indications in patients with the disease or condition under study and to determine the common short-term side effects and risks. • **II/III** - Trials that are a combination of phases II and III. • **III** - Includes expanded controlled and uncontrolled trials after preliminary evidence suggesting effectiveness of the medical approach has been obtained, and are intended to gather additional information to evaluate the overall benefit-risk relationship of the drug and provide an adequate basis for physician labeling. • **IV** - Studies of FDA-approved drugs, interventions, tests or diagnostic procedures to delineate additional information including the medical approach risks, benefits, and optimal use. • **NA** (Not applicable) - All non-interventional or pilot studies.
Pilot Trial?	If the trial is a pilot, select **Yes**.
Purpose	Select the primary purpose of the trial from the drop-down list. Valid values are as follows: • **Treatment**. Protocol is designed to evaluate one or more interventions for treating a disease, syndrome, or condition. • **Prevention**. Protocol is designed to assess one or more interventions aimed at preventing the development of a specific disease or health condition. • **Supportive Care**. Protocol is designed to evaluate one or more interventions where the primary intent is to maximize comfort, minimize side effects or mitigate against a decline in the subject's health or function. In general, supportive care interventions are not intended to cure a disease. • **Screening**. Protocol is designed to assess or examine methods of identifying a condition (or risk factors for a condition) in people who are not yet known to have the condition (or risk factor). • **Diagnostic**. Protocol is designed to evaluate one or more interventions aimed at identifying a disease or health condition. • **Health Services Research**. Protocol is designed to evaluate the delivery, processes, management, organization, or financing of health care. • **Basic Science**. Protocol is designed to examine the basic mechanism of action (e.g., physiology, biomechanics) of an intervention. • **Other**. Any purpose not described above.
Identifier Type	Select the type of trial identifier from the drop-down list. Valid values are as follows: • **NCI** - NIH National Cancer Institute identifier • **ClinicalTrials.gov (ClinicalTrials.gov Identifier)** - Provide the *exact* number, including the ClinicalTrials.gov Identifier prefix. Example: NCT00012345 • **Lead Organization** - Enter the unique identifier assigned to the trial by the lead organization • **Other identifier** - Additional trial identifier such as unique identifier from other registries, NIH grant numbers, or protocol numbers assigned by the Review Board **Selecting a Trial Identifier Type is not required** You can enter an identifier in the **Identifier** field without first having to choose an Identifier Type.
Identifier	Enter the unique identifier assigned to the trial by the NCI, ClinicalTrials.gov, PRS, or the identifier assigned to it by the lead organization. For Inter-Group trials, enter the Lead Group's trial number.
Organization Type	Select one of the following organization roles from the drop-down list: • **Lead Organization** - Returns all trials on which the selected organization is the Lead Organization • **Participating Site** - Returns all trials on which the selected organization is a Participating Site • **Both** - Returns all trials on which the selected organization is either the Lead Organization or Participating Site You can change the Organization Type without affecting any other search criteria you may have selected previously.

Organization	The system suggests organizations as you type. Enter the initial letter(s) of the organization and then select the organization from the list of suggestions. To search for trials by organization without having to specify what role the organization plays in the trial, select **Both** from the **Organization Type** list, and then select the name of the organization of interest.
Principal Investigator	The system suggests names as you type. Enter the initial letter(s) of the principal investigator's last name and then select the investigator name from the list of suggestions.
Search by Trial Category	To restrict your search by trial category, select *Abbreviated* or *Complete* from the drop-down list. Otherwise, select **Both**.

3. Click **Search.**
   The Search menu options are displayed.

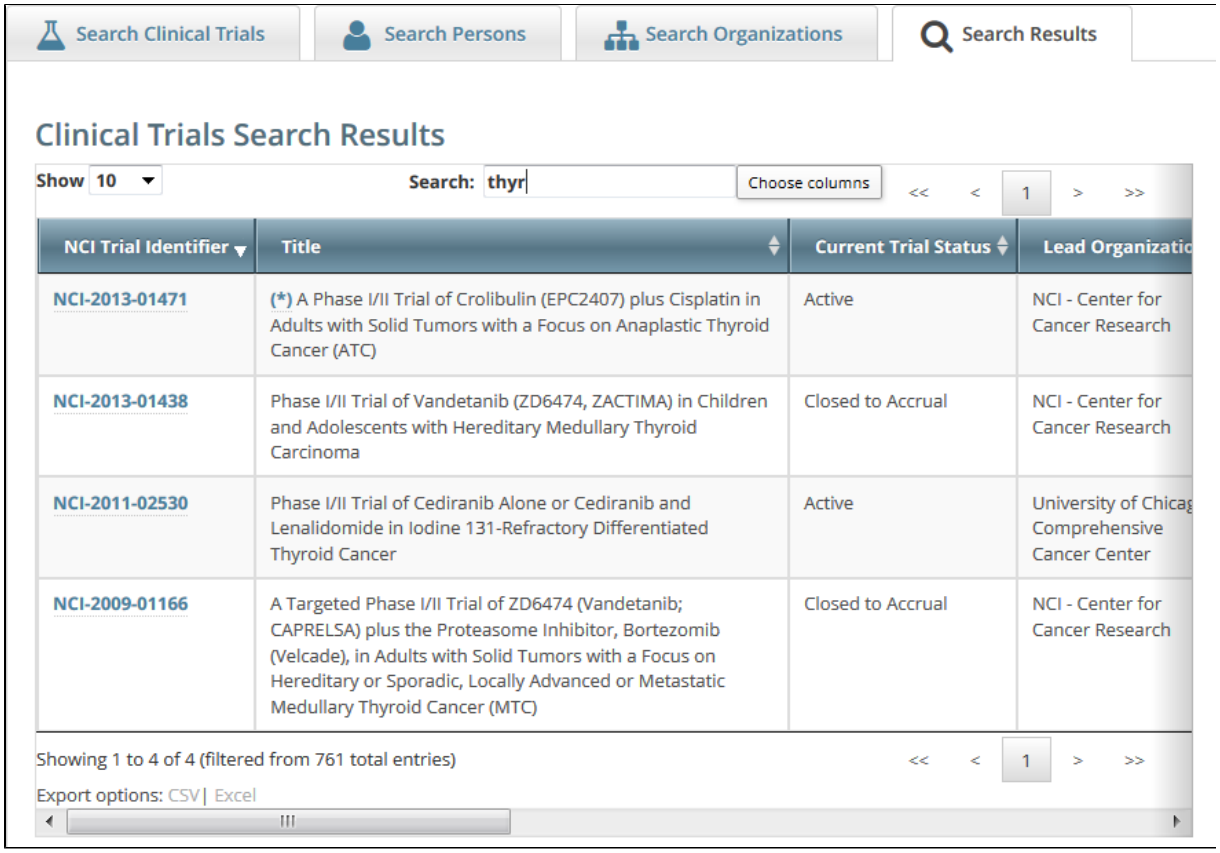


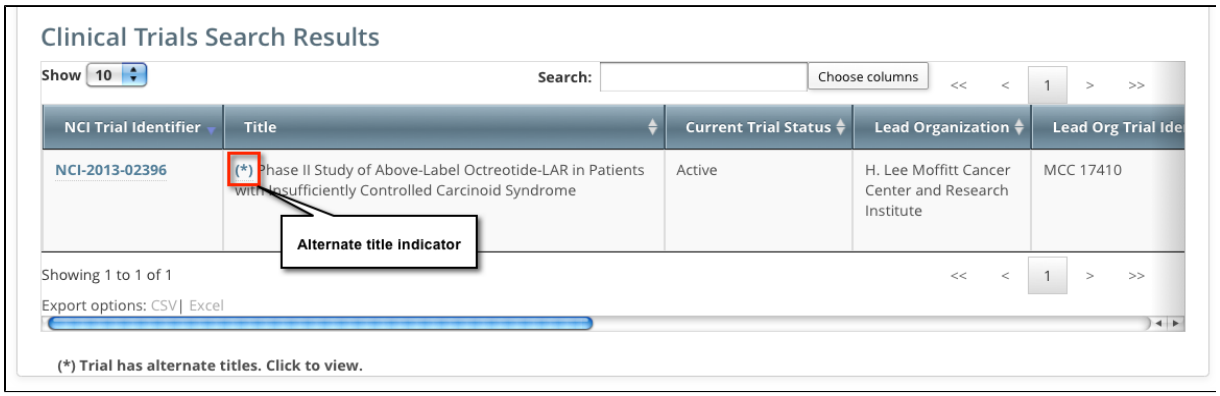
4. Do one of the following:
   - To search all registered trials in the system, click **All Trials**.
     -or-
   - To search only the trials that you submitted or own, click **My Trials**. This feature enables access to all the trials that you have submitted, including those that are currently on hold. (The Clinical Trials Reporting Office staff places trials on hold when they are unable to process a trial without further information, usually from the submitter.)

     -or-
   - To search only the trials that you have saved for later completion, click **Saved Drafts**.
     -or-
   - To clear all search criteria and begin a new search, click **Reset**.

   Allow sufficient time for the system to conduct your search before you run your search again
   The search is complete only when the system displays search results or alerts you that it could not find a trial to match your search criteria.

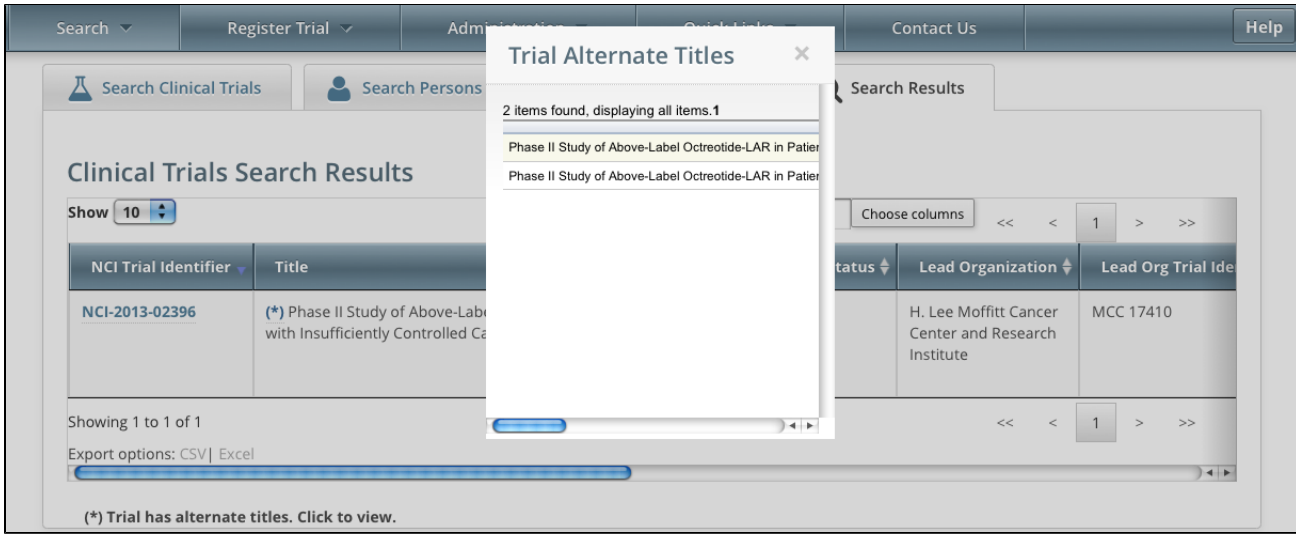
   The trials that meet your search criteria are listed on the **Search Results** page. For more information on navigating and working with search results, see Working with Tables and Search Results.





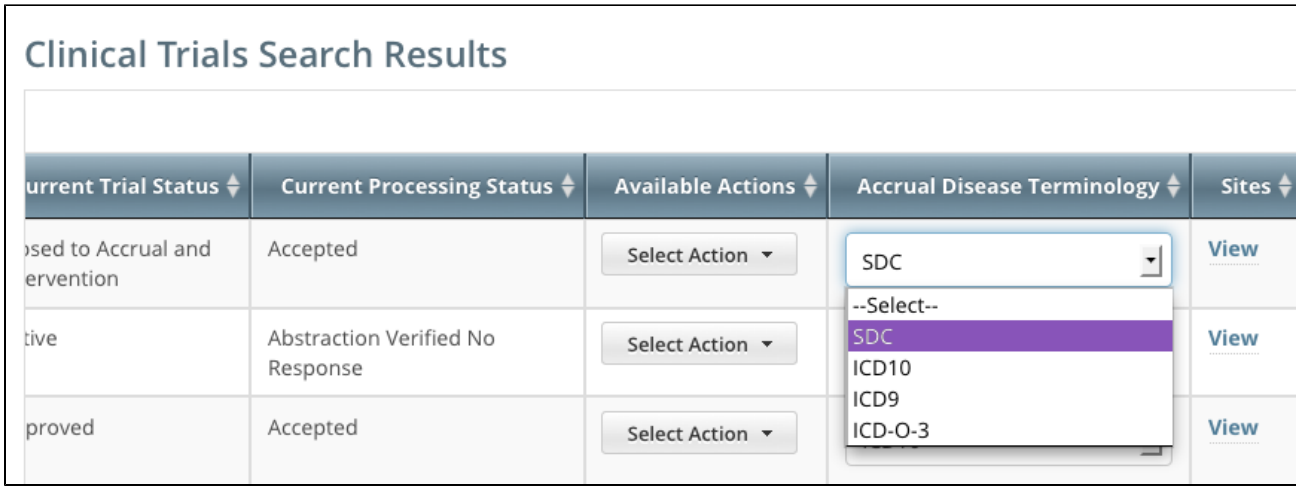
Trials may have more than one title. For example, the CTRO staffs may add an alternate title if they find a misspelling in the registered title. Any trial identified by more than one title is identified in the search results table by an asterisk (*) in the Title column.

5. To see the alternate titles associated with a trial, click the asterisk (link).
   The list of alternate titles is displayed in the Trial Alternate Titles window.



You can change Accrual Disease terminologies for individual trials
If you searched for "My Trials", the search results table displays an additional column, **Accrual Disease Terminology**. You can select a new terminology from the drop-down list only if the trial has *not* accrued patients.

Additionally, you can change accrual disease terminology at any time for trials currently recording accruals at the summary level only.



6. To view a trial, click its **NCI Trial Identifier** link.
   The Trial Details page appears. See Viewing Trial Details.

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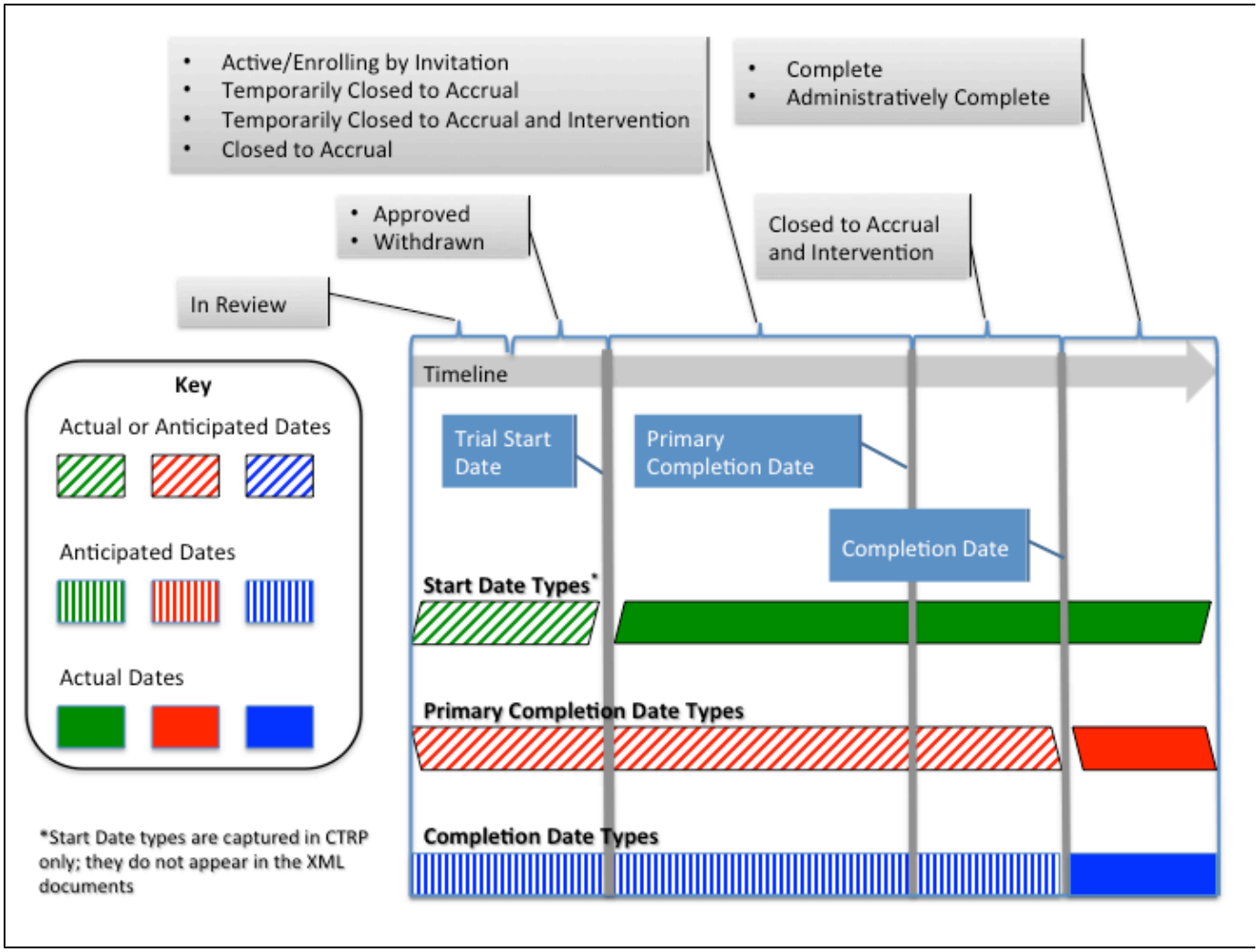
Trial Status Rules for Start and Completion Dates

Valid dates for a given trial status depend on the other values you have entered, and whether those dates are *Actual* (current, or past) or *Anticipated* (future).
The following diagram illustrates these rules. The arrow at the top of the diagram represents a time line for the life of a trial. The three horizontal bands in the lower section of the diagram represent, from top to bottom, the relative date (actual or anticipated) rules for trial Start Date types, Primary Completion Date types, and Completion Date types.



The following table provides the rules for trial status dates as diagrammed.

Rules for Status/Dates relationships

If this is true...	Follow this rule
Current Trial Status is anything *other than* In Review, Approved, or Withdrawn	Trial Start Date must be Actual (solid band)
Current Trial Status is Approved or In Review	Trial Start Date could be Actual or Anticipated (diagonal stripes band)
Current Trial Status is Complete	All date types must be Actual (solid band)

The general rules for Study Date types are as follows:

- If the date is in the past, the type must be actual.
- If the date is today, the type could be actual or anticipated.
- If the date is in the future, the type must always be anticipated.

The general rules for Study Date values are as follows:

- The Trial Start Date can be in the past, present, or future.
- The Primary Completion Date is always the same as, or later than, the Trial Start Date.
- If the Primary Completion Date is *Actual*, it can be earlier than the Current Trial Status Dates *Complete* or *Administratively Complete*.
- The Completion Date is always the same as, or later than, the Primary Completion Date.

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Updating Trials

As trial owner, you can update a subset of the information included with the original trial submission, including the following:

- **ClinicalTrials.gov Identifier** (other than Industrial/Other trials)
- **Other Identifier**
- **Local Trial Identifier** (Industrial/Other trials)
- **Title** (other than Industrial/Other trials)
- **Accrual Disease Terminology** (other than Industrial/Other trials)
- **NIH grant information** (for NIH-funded trials).

  > You can add grants but you can not update existing grant information.

- **Participating site**
  - Site recruitment status and associated date for abstracted trial sites. See Recording Trial Statuses and Dates .
- **Status dates**

  > Changing the overall trial status must reflect changes to the trial status at the site. For example, if you change the overall status from Approved to Active, you must change the recruitment status from Not Yet Recruiting to Recruiting.

- **Trial documents**

  > Documents you upload when using the Update Trial feature do not overwrite existing documents.

You can change the trial status information directly from the Search Results table without having to open the trial record. To use this method, in the Search Results table's **Action** column, select **Change Status** and make your changes as per the instructions in Recording Trial Statuses and Dates .

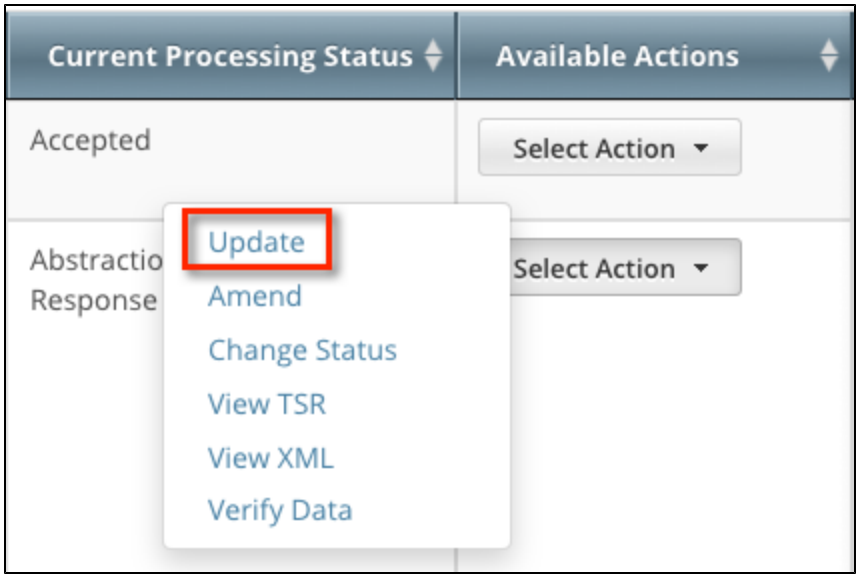
Protocol Document Updates

The Update Trial feature accommodates the following type of protocol document changes.

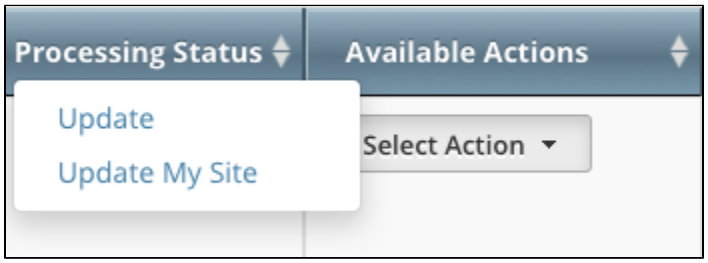
- **Editorial, Administrative Changes** (correction of minor typographical errors; clarifications made to previously approved descriptions of research)
- **Data, Data Collection, and Data Collection Materials** (revised study diaries; revised questionnaires or QOL surveys given to participants)
- **Recruitment of Subjects** (changes in the way subjects are recruited; a new or revised advertisement)
- **Principal Investigator Contact Information**

How to Update Trials

1. Click **Search > Clinical Trials**.
   The Search Trials page appears.
2. Click **Search > My Trials**.
   The Search Results table displays the results of your search and actions available (if any) for each record. For information about navigating the search results list, see Viewing Trial Details .

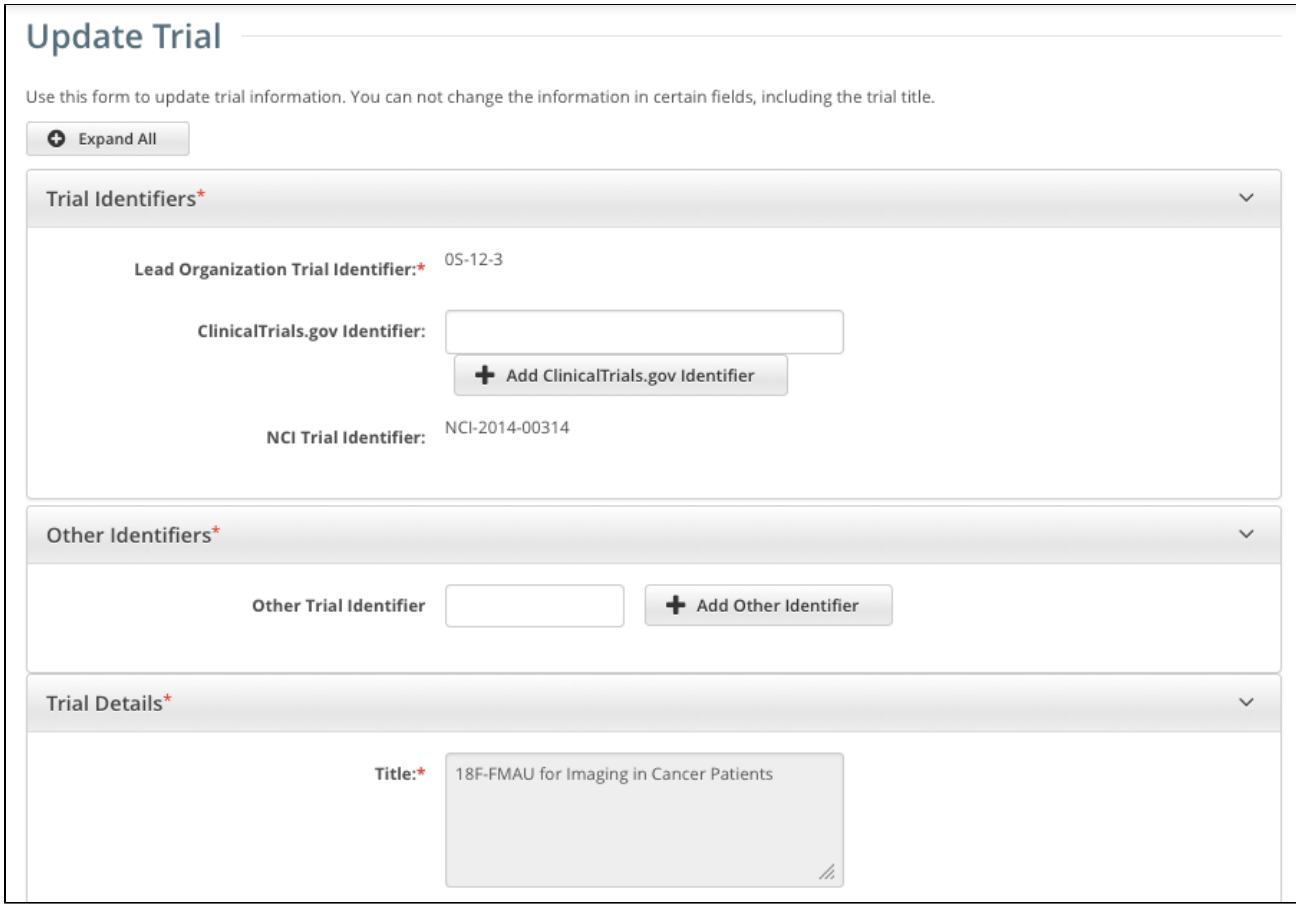


"Available Actions" Columns for Complete trials - Select Action List

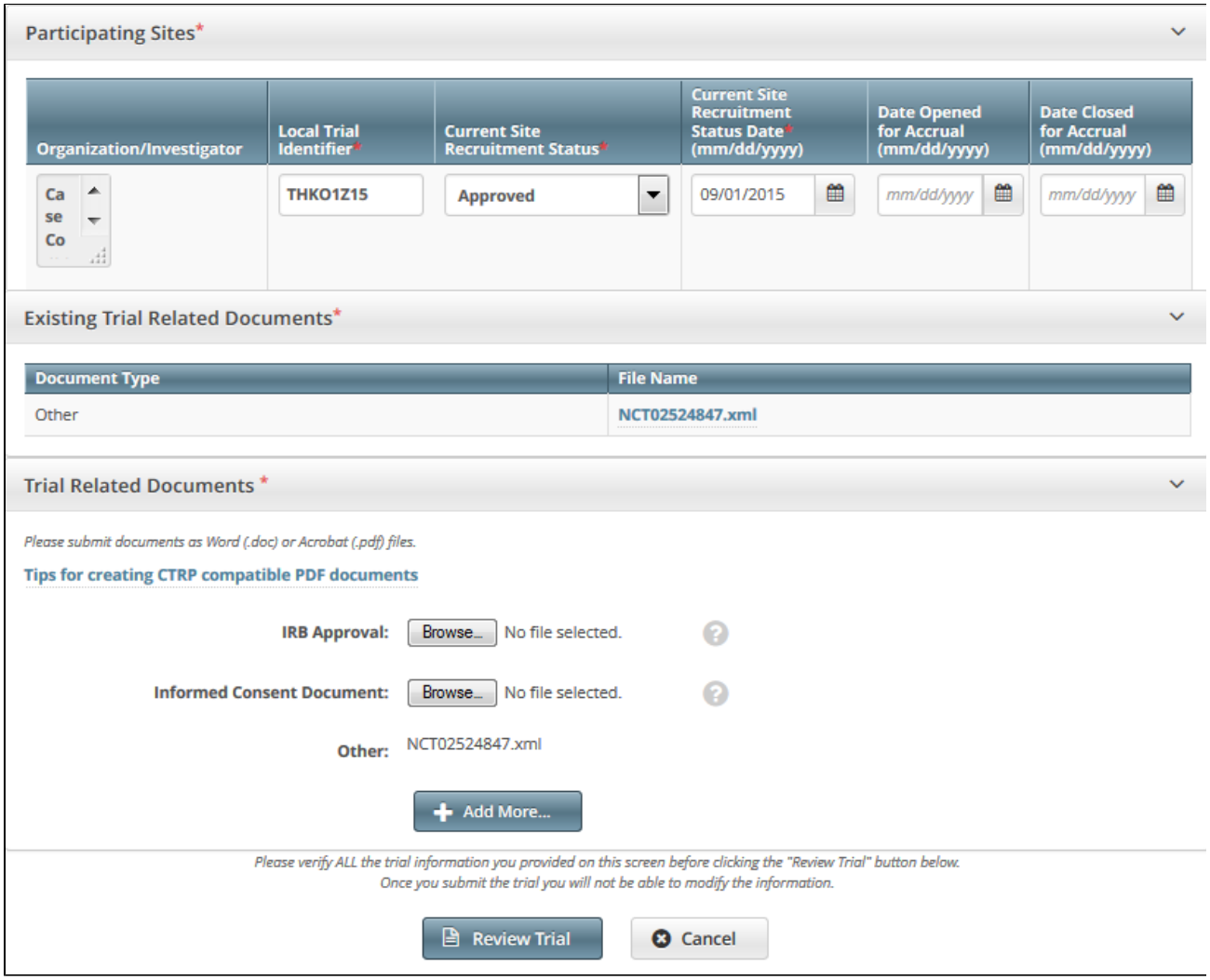


"Available Actions" Columns for Industrial trials - Select Action List

3. In the **Available Actions** column, click **Select Action > Update**.
   The Update Trial page displays the data currently registered with CTRP.

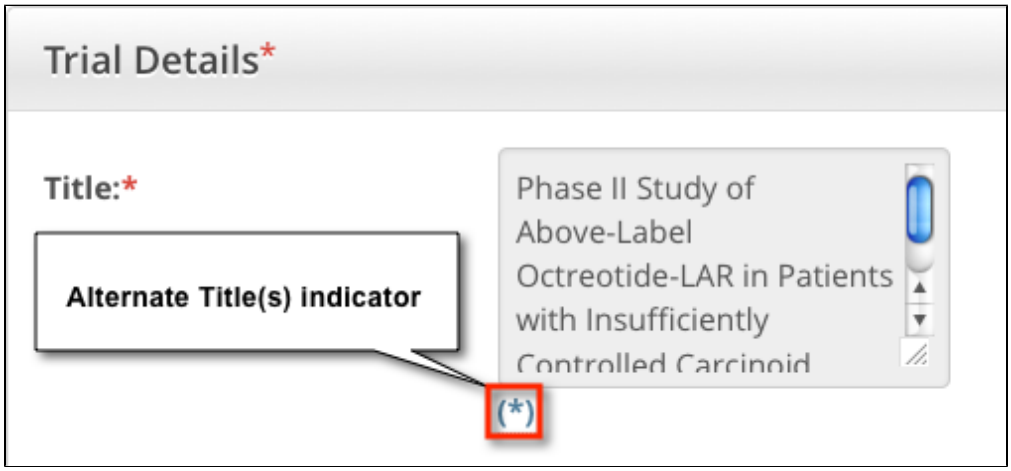


Update Trial page for Complete trials

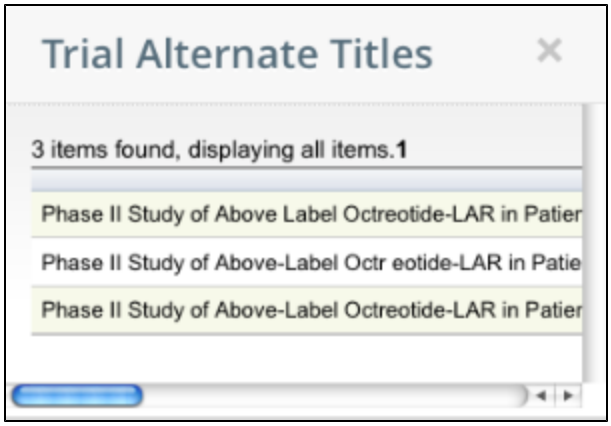


Update Trial page for Industrial trials

An asterisk (*) at the end of a trial title indicates that the trial has alternate titles.



4. To view the alternate titles, click the asterisk (*)



5. If applicable, enter an ClinicalTrials.gov Identifier, and then click **Add ClinicalTrials.gov Identifier**.

> You cannot change the ClinicalTrials.gov Identifier once you have added it. If you need to make changes thereafter, contact the CTRO at NCICTRO@mail.nih.gov.

> When you submit the trial, the system checks the NCT number you entered to ensure that no other registered trial has the same one. The system displays an error message if it finds another trial with the same NCT number. If this occurs, check the number you entered and try again. If you are certain that the number you entered is correct, contact the CTRO at NCICTRO@mail.nih.gov.

6. Make changes to the fields as necessary. Instructions for recording each of the fields are provided in Registering New Trials .
7. If appropriate, upload any new or updated documents. See Recording Trial-Related Documents .
   If you upload an IRB document, the CTRO reviews the updated record you submit and makes changes to the record as necessary. For example, if you upload an IRB document for a trial currently in the In Review state, the CTRO updates the IRB information section of the trial record (e.g., IRB status and approval number).
8. To review the information you provided, click **Review Trial**.
   The system checks the updated information for errors, and displays the results at the top of the Update Trial page.
9. If necessary, correct any errors, and click **Review Trial**. Repeat this cycle until your update is error-free.
10. Submit the trial update.
    The system sends you an update notification—with the details of what has changed—whenever you update accepted trials.

> A trial can accumulate program codes from different organization families. For example, a participating site might belong to a different organization family than the lead organization. When you update a trial, the Program Code field displays all codes from the master list for the organization family of the lead organization.

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Verifying Trial Data

NCI requires that trial owners, trial submitters, and members of the Clinical Trials Reporting Office (CTRO) staff verify their open trial records twice per year to ensure that information is accurate and up-to-date.

This requirement applies to Interventional trials that have the following attributes:

- Trial processing status is either Abstraction Verified - No Response or Abstraction Verified - Response
- Trial status is anything other than the following:
  - Withdrawn
  - Administratively Complete
  - Complete

> CTRO staffs are responsible for verifying the types of trials below. Trial owners and submitters are responsible for verifying all others.
>
> - NCI-managed trials (trials with DCP or CTEP IDs)
> - NCI-sponsored trials

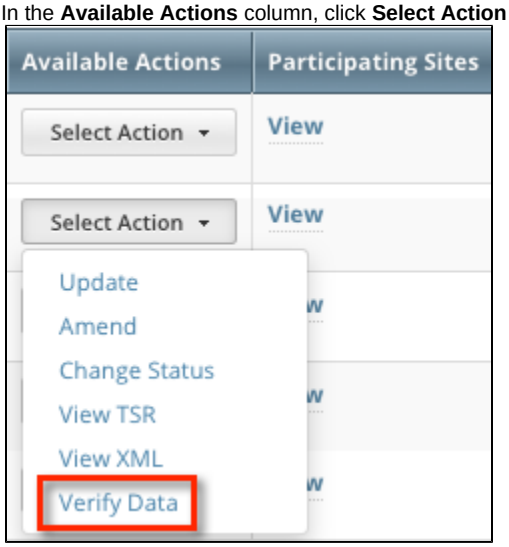
- Trials imported from ClinicalTrials.gov
- Trials submitted by users affiliated with the National Cancer Institute or National Cancer Institute Division of Cancer Prevention
- Trials submitted by the NCI Center for Cancer Research (CCR)

The system sends trial owners, trial submitters, and site administrators a verification reminder 30 and 15 days before their trial data verification due dates. It sends reminders to CTRO staffs 7 days before the due date.

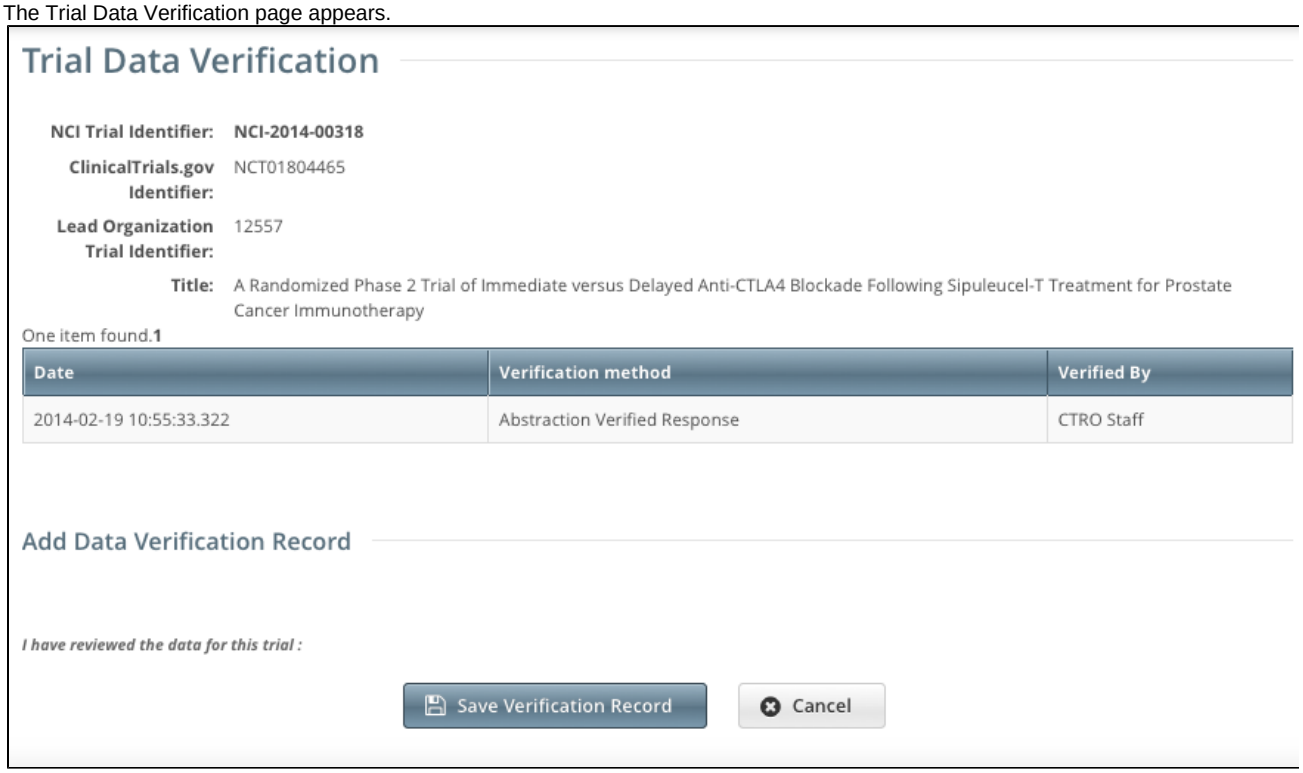
Each time you verify a trial, the CTRP system records your name and date of verification. This is true for original as well as updated trials. You can view these records at any time, but cannot change them.

How to Access the Trial Data Verification Page

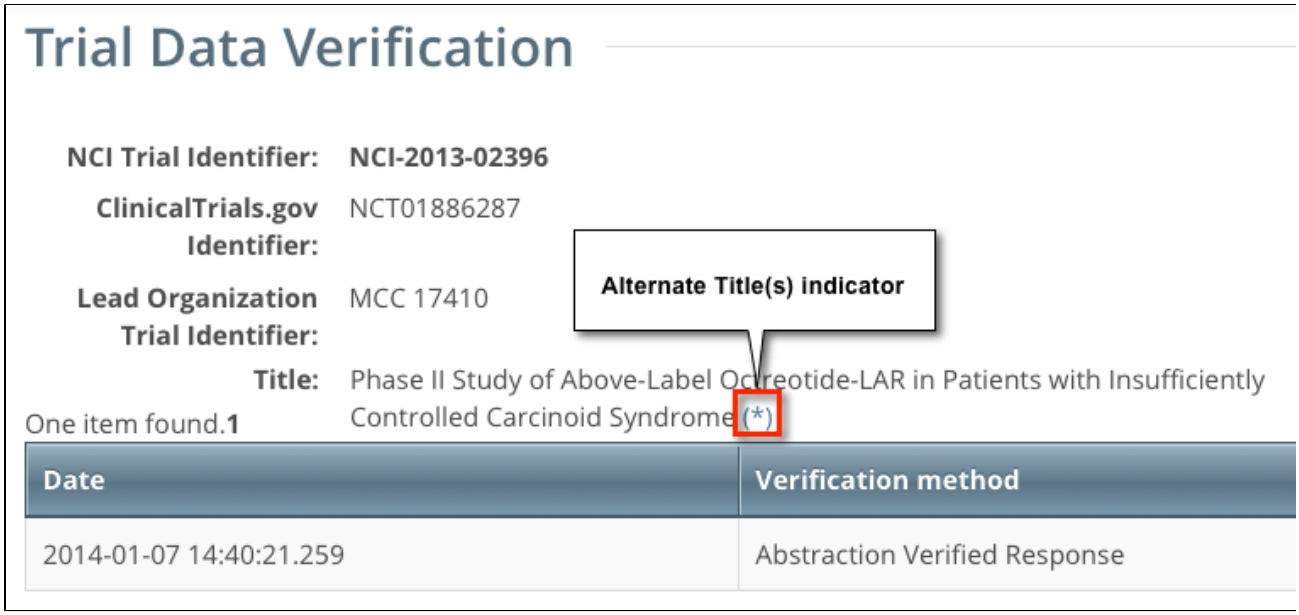
1. Search for the trial by the identifier noted in the email reminder you received, or use the **Search My Trials** feature.
2. In the **Available Actions** column, click **Select Action > Verify Data**.



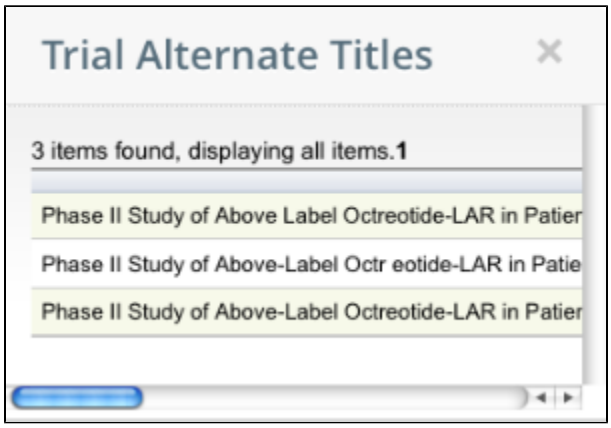
The Trial Data Verification page appears.



An asterisk (*) at the end of a trial title indicates that the trial has alternate titles.



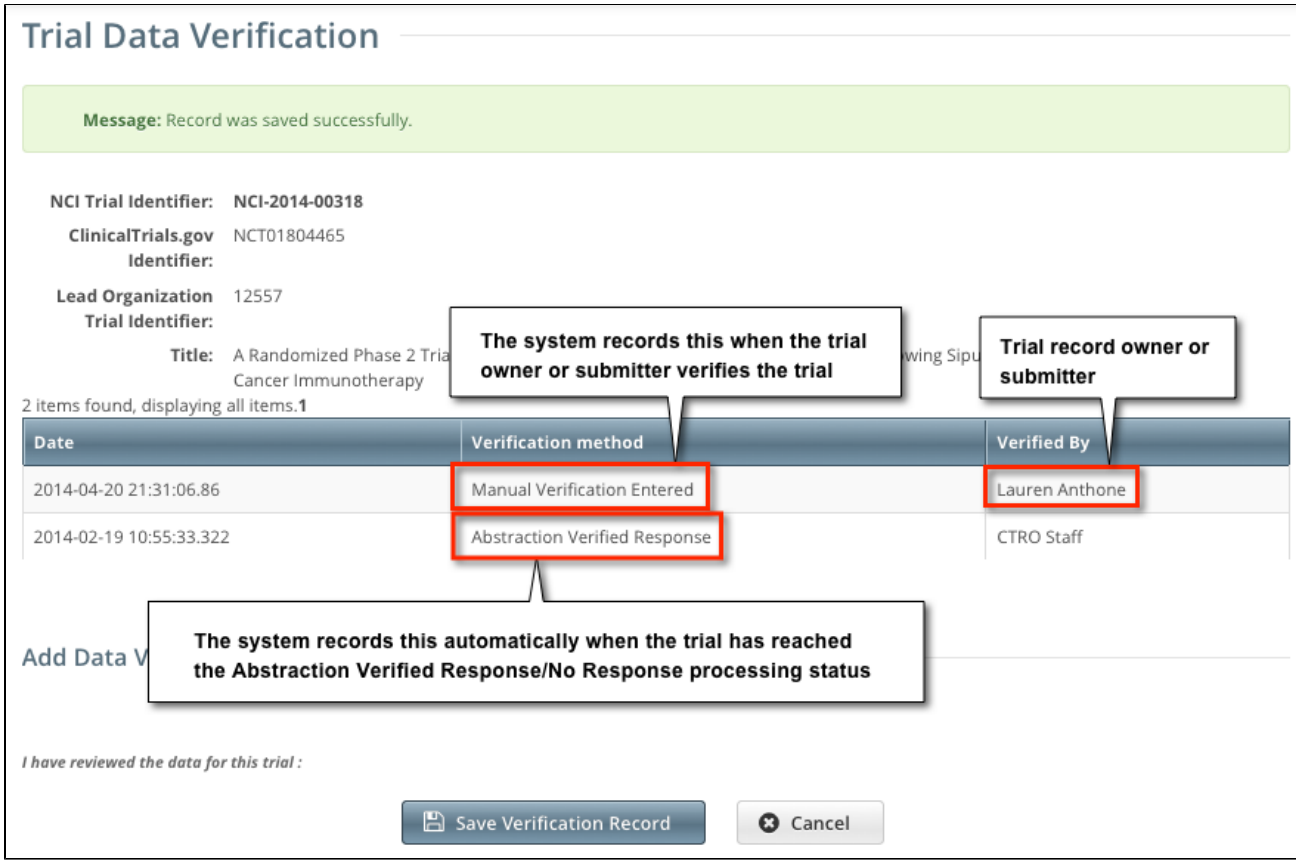
3. To view the alternate titles, click the asterisk (*)



How to Verify Trial Data

1. On the **Trial Data Verification** page, under **Add Data Verification Record**, click **Save Verification Record**.
2. Confirm that you would like to save the record by clicking **OK** in the pop-up message.

   The Trial Data Verification page displays all verification records to date.



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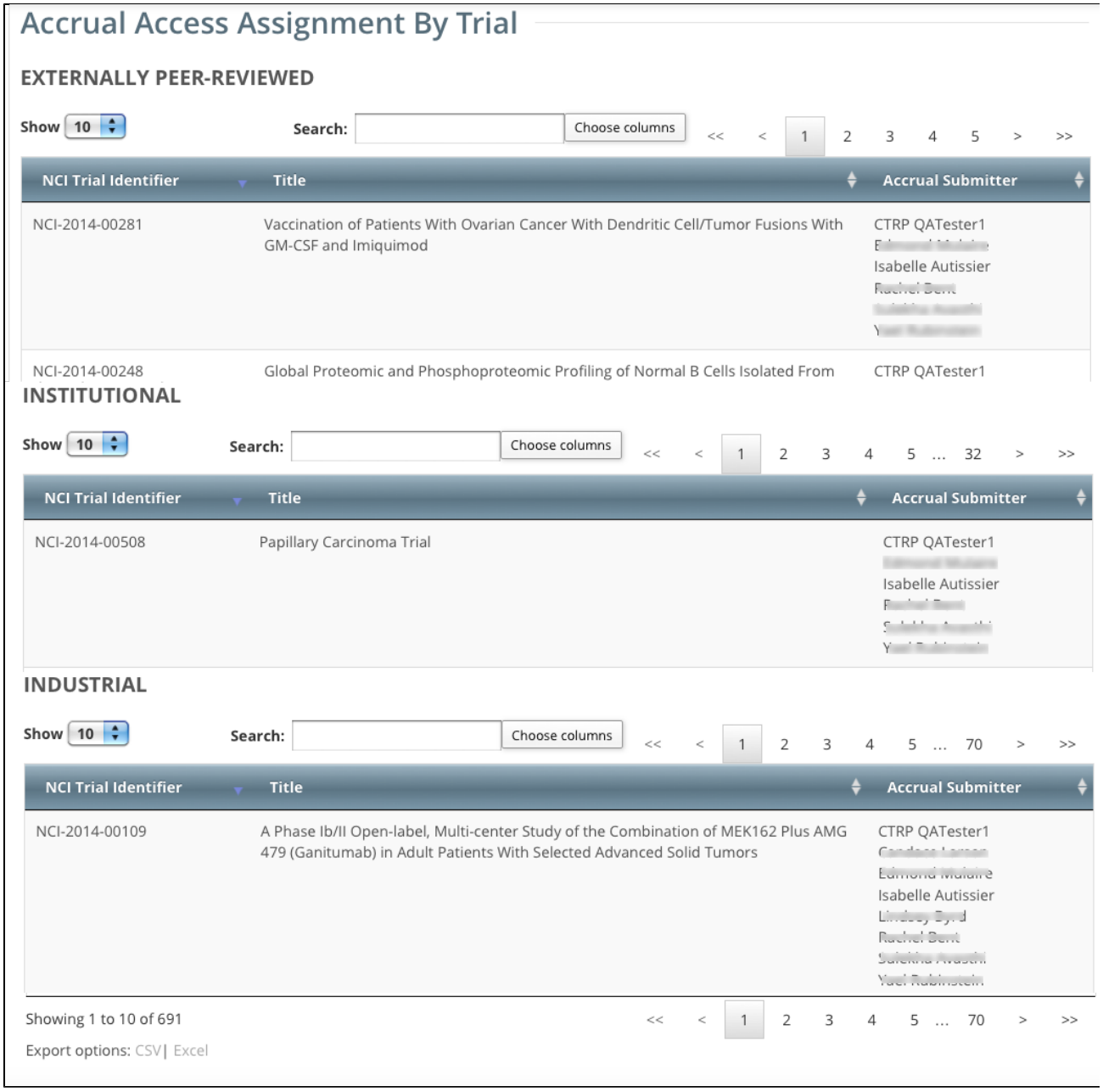
Viewing Accrual Assignment History by Trial

As a site administrator, you can view a history of your organization's accrual access assignment on a per-trial basis.

How to View Accrual Assignment History by Trial

1. On the toolbar, click **Administration** > **Accrual Access** > **View**.
   The Accrual Access Assignment by Trial page lists all current access assignments by trial, grouped by trial category.



To navigate the table, refer to Working with Tables and Search Results .

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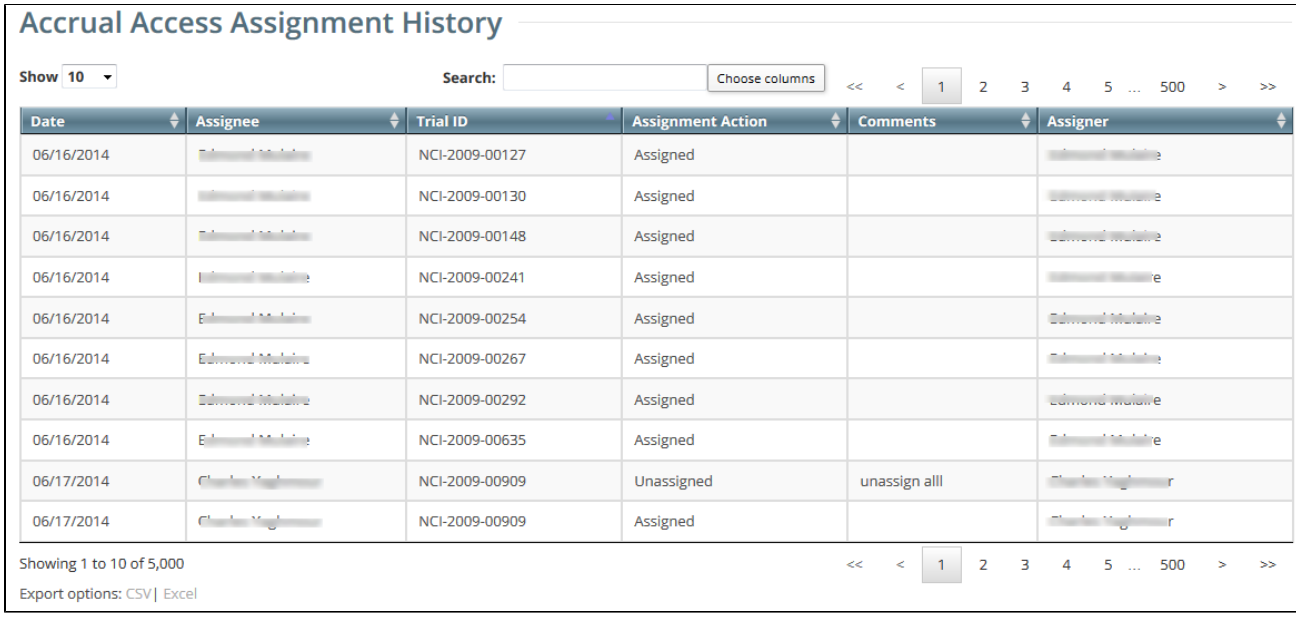
Viewing Accrual Assignment History in Registration

As a site administrator, you can view a history of your organization's trials to which users have been assigned/unassigned user access.

How to View Accrual Assignment History

1. On the toolbar, click **Administration** > **Accrual Access** > **Assignment History**.
   The Accrual Assignment History page lists all access assignments and assignments.



2. To navigate the table, refer to Working with Tables and Search Results .
3. To export the assignment history to a file, click **CSV** (comma-separated values) or **Excel** in the bottom left corner. Your browser prompts you to open or save the file.

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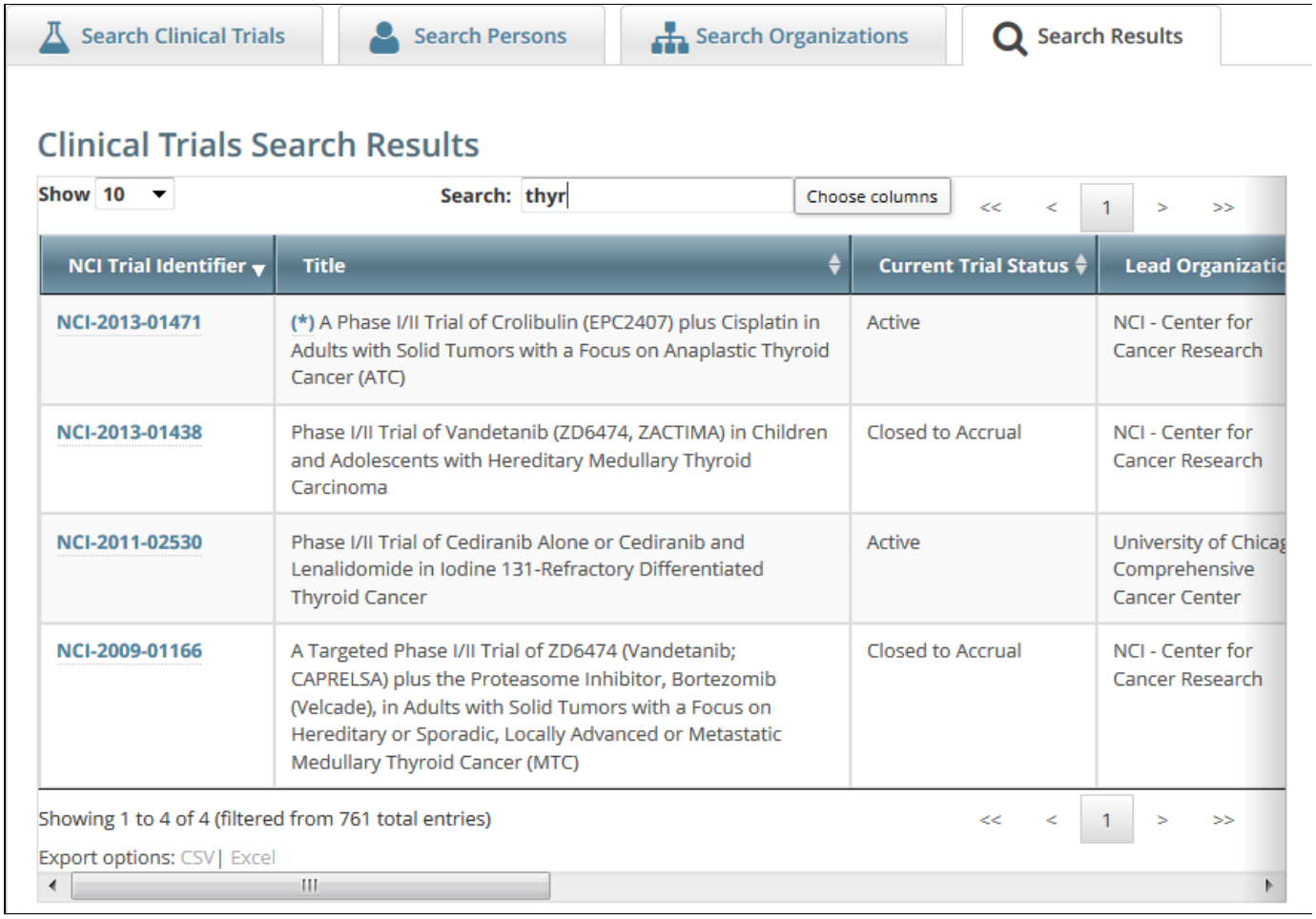
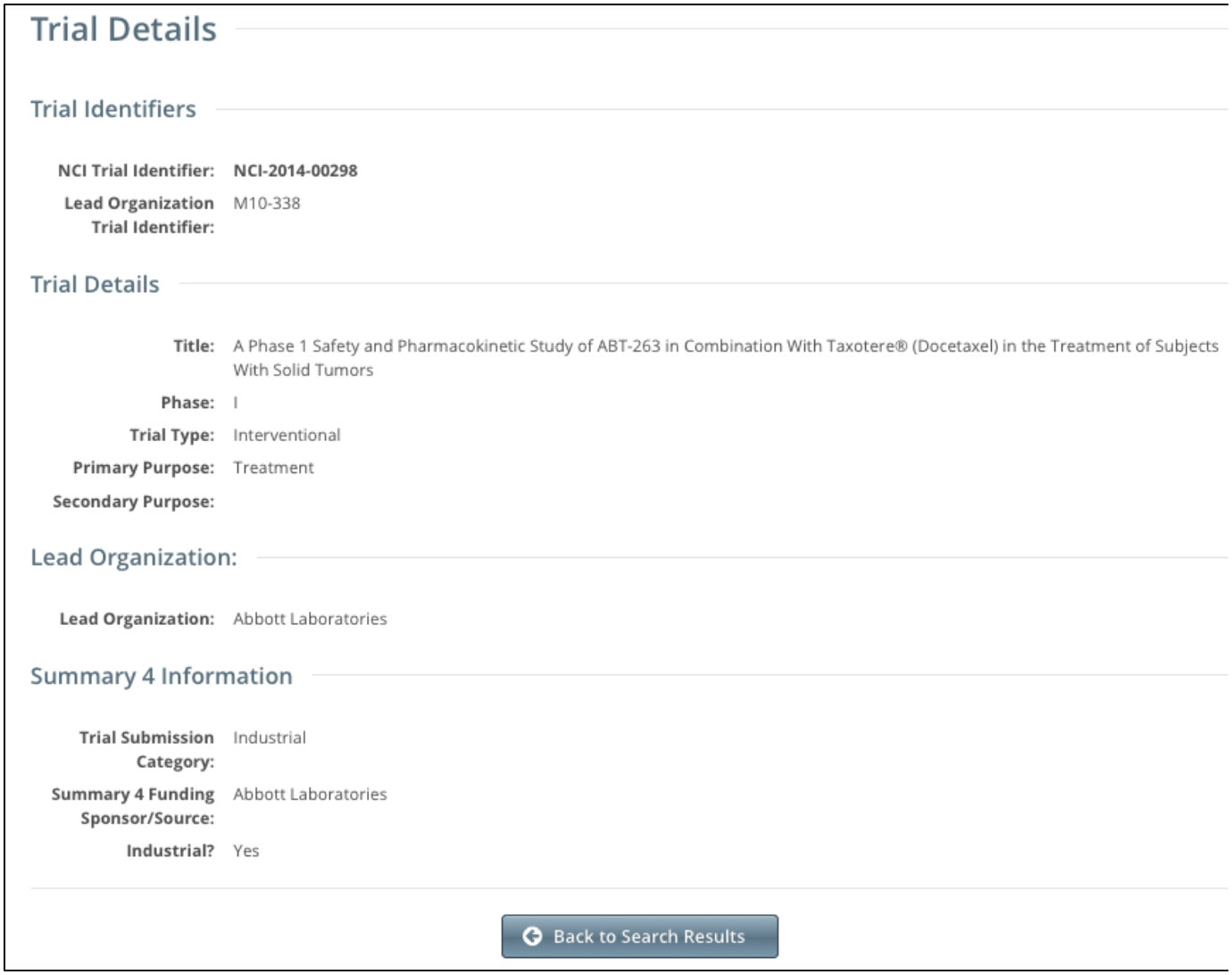
Viewing Trial Details

Trials you search for are listed in the Submitted Clinical Trials Search Results table as shown below.



To view details for a given clinical trial listed on a search results page, click its associated **NCI Trial Identifier** hypertext link.
The details provided for a given trial depend on trial ownership (private or public) and Data Table 4 Category (*Complete* or *Abbreviated*).

The Trial Details page displays the metadata as entered by a trial submitter. The upper part of the Trial Details page is shown below. Refer to the Glossary of CTRP Terms for a description of the metadata.



Responsible party, IND/IDE, NIH grant information and trial-related documents are only displayed for Private trials.

To return to the **Search Trials** page, scroll to the bottom of the **Trial Details** page, and click **Back to Search Results.**

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Working with Search Results

The Clinical Trials Reporting Office (CTRO) reviews each trial submitted to the system in order to validate submitted information. During the validation process, the reviewers check for duplicate records and ensure that the submitter has provided all required information. CTRO does one of the following as part of the validation/abstraction process:

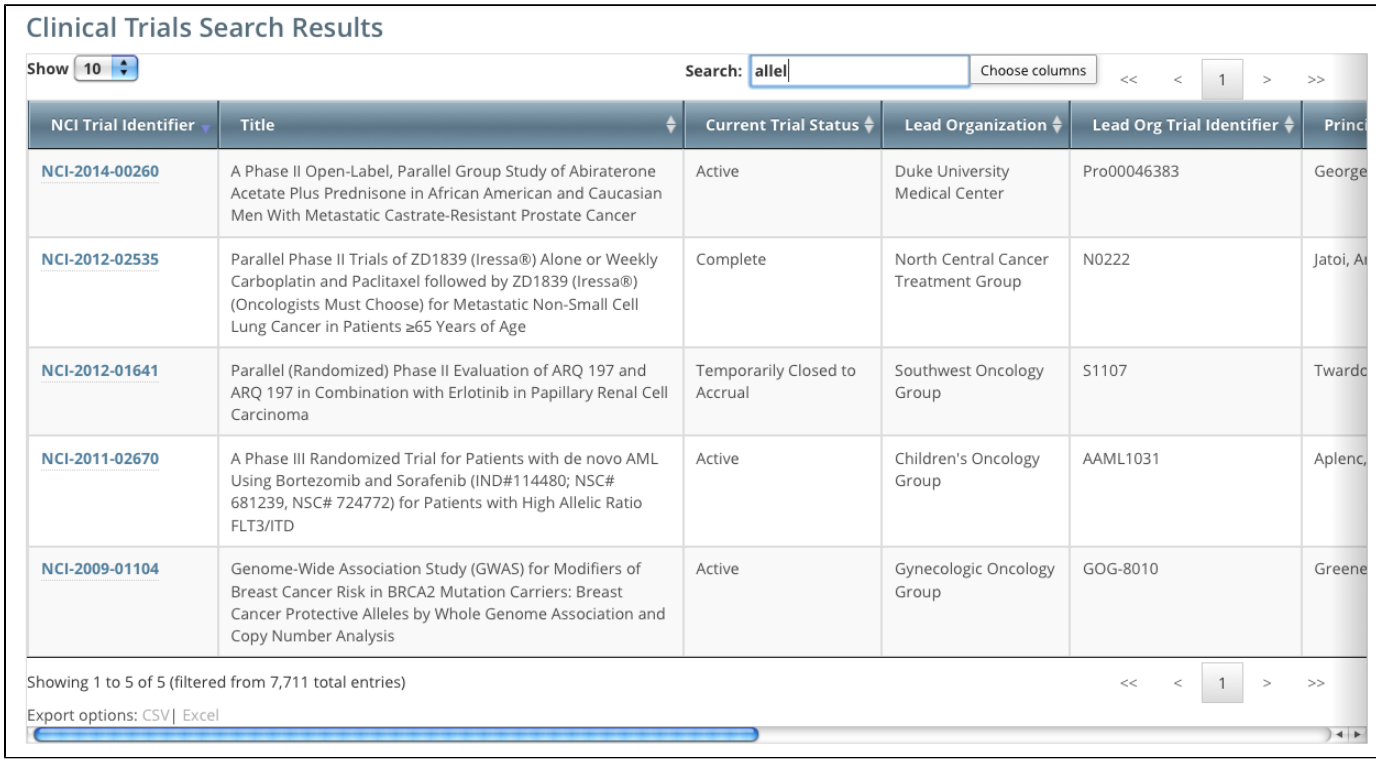
- If all data is complete and accurate, the reviewers assign the trial the status "Accepted," and the system notifies the submitter by email.
- If information is missing, or there are discrepancies in the information provided, the reviewers can place a trial on hold. The CTRO contacts the submitter for clarification and/or to request missing documents, and resumes processing once the trial is validated.
- If the trial is a duplicate (i.e., another user has submitted the same trial), the reviewers assign the trial the status "Rejected," and the system sends the submitter an email message indicating the status and reason for the rejection. Reviewers may also reject a trial if CTEP/DCP/CCR has approved the trial. NCI transfers these trials internally.

If you have questions about a rejected trial, contact the CTRO at ncictro@mail.nih.gov.

The trials that match your search criteria are listed in search results tables. Which of the search results are displayed is determined by the following criteria:

- Processing status of the trial at the time of the search. Trial statuses are listed and defined in Trial Processing Statuses.
  - **Submitted** - Original trial submitted but not validated
  - **Amendment Submitted** - Amendment submitted but not validated
  - **Accepted** - Trial passed validation
  - **Rejected** - Trial did not pass validation. These trials are not displayed.
  - **Abstracted** - Trial has been abstracted
  - **Verification Pending** - Trial has been abstracted, and the Trial Summary Report (TSR) has been sent to the trial submitter for abstraction verification
  - **Abstraction Verified Response** - Submitter has verified the abstraction as per the TSR, and has returned feedback to the CTRO within five business days after receiving the TSR
  - **Abstraction Verified No Response** - Submitter has not responded or returned verification feedback to the CTRO within five business days after receiving the TSR
- User's role with respect to the trial. User roles include the following:
  - **Site Administrator** - Has full access to the trials led by the organization (plays lead organization role)
  - **Trial Submitter/Owner** - Has full access to the trials they own or submitted
  - **Other user** - Any user other than the trial submitter, owner, or trial's lead organization system administrator
- **Trial ownership**. Trial ownership types are as follows:
  - **Private trials** - Trials submitted or owned by the user who is currently logged in to Registration
  - **Public trials** - Trials submitted by other registered users

(A business day is any weekday that is not a Federal holiday. For a list of Federal holidays, refer to the U.S. Office of Personnel Management's list of Federal Holidays.)



To navigate the search results table, see Working with Tables and Search Results.

Trial records returned from "Search My Trials" and "Search All Trials" options display the following details and actions you can take for each trial when applicable.

> No data are displayed for Private trials with a processing status of Rejected nor for Public trials with a processing status of Submitted or Rejected.

The following table describes the columns in the search results table:

Column	Displayed for Public trials?	Description
NCI Trial Identifier	Yes	Unique identifier assigned to the trial by the CTRP
Title	Yes	Official name of the protocol provided by the study principal investigator or sponsor (same as in the protocol document)
Lead Organization	Yes	Organization responsible for the overall scientific and administrative coordination, study monitoring, and data management activities of a given clinical trial
Lead Org (Organization) Trial Identifier	Yes	Unique identification assigned to the protocol by the sponsoring organization, usually an accession number or a variation of a grant number. Multiple studies conducted under the same grant must each have a unique number.
Principal Investigator	Yes	Appointed investigator responsible for conducting the clinical trial, or, for multi-site trials, the study chair
ClinicalTrials.gov Identifier	Yes	Number assigned to the trial by PRS (ClinicalTrials.gov) (for trials that have been submitted to ClinicalTrials.gov previously)
Other Identifiers	Yes	Identifiers other than Lead Organization Trial Identifier or ClinicalTrials.gov Identifier
Current Trial Status	Yes	Code that represents the status of a trial in relation to the ability to enroll participants/patients
Current (Trial) Processing Status	No	Stage in the trial processing work flow
Available Actions	Yes	Actions that are applicable to the trial according to the processing rules • Update - Link used to initiate trial updates • Amend - Link used to initiate trial amendments. Available for trials with processing statuses abstraction verified (response/no response). • Change Status - Link used to initiate a change to the trial status and status dates • Add My Site - Link used to initiate adding an organization as a participating site • Update My Site - Link available to Participating Site Record owners to initiate participating site information changes • Request TSR and XML documents (for complete trials) - Documents are sent via email to all trial owners • Verify Trial Data - Link used to verify open trial records twice per year to ensure that information is accurate and up-to-date The actions available for a trial depend on its processing status and participating site record ownership.
Accrual Disease Terminology	No	The disease terminology currently in use for accruals. You can select a new terminology from the drop-down list only if the trial has not accrued patients. Additionally, you can change accrual disease terminology at any time for trials currently recording accruals at the summary level only.
(Participating) Sites	Yes	One or more organizations participating in the trial. Click **View** in the **Sites** column to view participating site details.
Phase	No	Phase of the investigation, as defined by the US FDA for trials involving investigational new drug
Primary Purpose	No	Main purpose of the trial
Category	No	Data Table 4 Funding Sponsorship or Trial Submission Category
Trial Start Date	No	Date on which the trial starts
Responsible Party	No	Responsible party, as defined by FDAAA
Sponsor	No	Primary organization that oversees the implementation of the study and is responsible for data analysis as defined in 21 CFR 50.3

Data Table 4 Funding Sponsor Type	No	Trial category selected for trial submission
Record Verification Date	No	Date on which the CTRO validated the trial submission
Submitter	No	Name of person who submitted the trial
Primary Completion Date	No	Date on which the trial reaches/reached its primary completion date
Last Update Submitted	No	Date on which the trial was last updated
Last Updater Name	No	Name of the person who last updated the trial
Last Amendment Submitted	No	Date on which the trial was last amended
Last Amender Name	No	Name of person who amended the trial
On-Hold Reason	No	Reason why the trial was placed on hold

Trial records returned from "Search Saved Drafts" display the following details and actions you can take for each trial when applicable:

Column	Description
Temporary Trial Identifier	Unique identifier that the system assigned to the saved draft
Title	Official name of the protocol provided by the study principal investigator or sponsor (same as in the protocol document)
Lead Organization	Organization responsible for the overall scientific and administrative coordination, study monitoring, and data management activities of a given clinical trial
Lead Organization Trial Identifier	Unique identification assigned to the protocol by the sponsoring organization. Multiple studies conducted under the same grant must each have a unique number
Action	• Complete - Link to initiate trial record completion • Delete - Link to initiate trial deletion

Trial ownership and current processing status determine which of the trial details and actions listed above are displayed in the Search Results table. Refer to Trial Processing Statuses.

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